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13. ABSTRACT (Maximum 200 Words)

This proposal evaluates interindividual differences in the response to genotoxic stress as prostate cancer risk factors. To this end we use measurements of mutagen sensitivity, apoptosis, comet assay, and single nucleotide polymorphisms in DNA repair genes OGG1 and XRCC1. These biomarkers are evaluated in 100 prostate cancer cases and 100 controls matched on age and race in order to measure response to bleomycin exposure is short-term cultured lymphocytes to define prostate cancer risk. We designed a new protocol, study questionnaire, updated consent forms and recruitment brochures to establish a case-control study of prostate cancer. During the second year of funding, we recruited 51 prostate cancer cases and 40 matched controls at the Georgetown University Hospital. A research assistant created a sample repository consisting of serum, plasma, buffy coat, urine, toenail clipping and saliva for every participant. We also created a computerized database of the samples in Microsoft Access. The research assistant measured mutagen sensitivity in all the subjects and determined the mean breaks in lymphocytes exposed to bleomycin in cases (mean 0.88 SD 0.32) and controls (mean 0.74 SD 0.34). We continue to optimize the apoptosis and comet assay protocols to measure DNA repair kinetic and cell death in exposed cells. We expect to proceed rapidly with the case-control study in the third year.

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Table of Contents

Introduction: Despite the fact that prostate cancer is the most common tumor among US males, relatively little is known about the causative mechanisms. The known risk factors include age, ethnicity or race, high-fat diet and family history of prostate cancer, but these factors are not sufficient for identification of men with increased susceptibility. Establishing new biomarkers of cancer risk would greatly benefit the field of prostate cancer prevention and surveillance.

Molecular epidemiology can elucidate prostate cancer risk factors by applying biomarker measures to population based methodologies. This is a case-control study testing variation in the response to genotoxic stress as a biomarker of prostate cancer risk. The study evaluates mutagen sensitivity, apoptosis, and polymorphism in *OGG1* and *XRCC1* as biomarkers of prostate cancer risk; the study also provides preliminary data on comet as an alternative biomonitoring tool.

Mutagen sensitivity is an established biomarker of risk (1). Comet assay is an increasingly popular tool for human biomonitoring (2) with the potential to identify cancer-prone individuals in the general population (1). Both comet assay and mutagen sensitivity measure DNA damage in short-term cultured human lymphocytes exposed to bleomycin (or other mutagens) as either tail moment (comet assay) or number of chromatid breaks (mutagen sensitivity). While mutagen sensitivity is an established tool in population-based studies of cancer risk and was associated with increased risk of glioma, lung, colon, hepatocellular, and HN carcinoma, comet assay was used only recently in three pilot studies of breast, cervical, and lung cancer (1). Surprisingly, neither assay was used to study prostate cancer risk. Even though the exact mechanism underlying these phenotype is unknown, variability in DNA-repair capacity is consistent with the available experimental results (3). Moreover, it was shown in twin studies that mutagen sensitivity is heritable in non-cancer subjects. The correlation coefficient was 0.79 (95% confidence interval = 0.65-0.88) in monozygotic twins while for dizygotic twins the coefficient was 0.42 (95% confidence interval = 0.00-0.71) (4). Mutagen sensitivity phenotype therefore reflects multiple genetic traits related to DNA repair capacities, which predispose an individual to cancer risk. Comet assay has several advantages compared to mutagen sensitivity: 1. An independent measure of DNA repair; 2. Higher throughput, better reproducibility and quantification, and lower cost per assay; and 4. Smaller sample size (also called SCGE, single cell gel electrophoresis assay) (2). We propose to compare the use of comet assay and mutagen sensitivity for screening of prostate cancer susceptibility.

Apoptosis is a molecular pathway eliminating, besides other functions, cells unable to cope efficiently with genotoxic stress. Deficient apoptosis is a likely candidate for a cancer-prone phenotype. Apoptosis was implicated in regulation of response to radiation therapy in prostate cancer (5), malignancy of prostatic tumor (6), and recurrence of prostate carcinoma following surgery (7). For example, in 54 prostate cancer patients treated with radiotherapy the response was negative in 84% cases with positive bcl-2 immunohistochemistry and bcl-2 was an independent prognostic variable for treatment with odds ratio of 7.3 (5). Apoptotic index was associated with disease recurrence in a study of 47 men following radical prostatectomy (7). But apoptosis was not yet examined as a phenotypic predictor of prostate cancer risk. Since the apoptotic phenotype is a composite measure of a number of converging mechanistic pathways, it is advantageous to the measurement of each individual genotype in the pathway.

DNA repair consists of two major categories, excision repair (base excision repair and nucleotide excision repair) and recombination repair (homologous and non-homologous) (8). Numerous polymorphisms in the DNA repair genes have been identified (9) and are likely to contribute to cancer risk through decreased efficiency of response to genotoxic stress. But two functional polymorphisms in DNA repair genes, *OGG1* and *XRCC1*, are particularly relevant to this study. Both genes are involved in the repair of 8-hydroxy-guanine (8-OHdG) and other oxidative lesions (10); and our study examines mainly how variability in the response to oxidative DNA damage modifies risk for prostate cancer (bleomycin is a radiomimetic which induces oxidative DNA damage and mutagen sensitivity is mainly a model of this pathway). OGG1 is a DNA glycosylase/AP lyase involved in base excision repair of 8-OHdG and XRCC1 is a DNA ligase III terminating the base excision repair cascade (10). The OGG1 Ser(321)Cys polymorphism codes for a protein with a lower 8-OHdG repair capacity and leads to several splicing variants of unknown functional significance (11). This variant occurs at a frequency of 0.4 in Japanese and was associated with an increased risk of lung cancer in a study of 241 cases and 197 controls with an OR=3.01 (95% CI 1.33-6.83) (12). This variant was found in a Caucasian population at a frequency of 0.22 and was not associated with lung cancer in this study (13). Examination of this polymorphism in prostate cancer is therefore highly relevant. The XRCC1 Arg(399)Gln polymorphism was associated with increased sensitivity of human lymphocytes to DNA damage (14), increased risk of squamous cell carcinoma of the head and neck (15), increased risk of early onset colorectal carcinoma (16), and increased risk of adenocarcinoma of the lung (17). The polymorphism occurs in 37% of Caucasians and 17% of African-Americans (19). An examination of the XRCC1 'at risk' polymorphism as a risk factor for prostate cancer was not reported.

The proposal is innovative because the proposed biomarkers were to our knowledge not examined in connection with prostate cancer risk. If mutagen sensitivity, comet assay, apoptosis, or DNA repair-variants correlate with prostate cancer risk, they could serve as readily obtainable biomarkers to identify men with increased risk of prostate cancer. The phenotypic biomarkers could be used to better identify the currently poorly understood genotoxic insults leading to cancer risk (improved risk models in case-control studies). Elucidating mechanisms of the early stages of prostate carcinogenesis would have an immediate impact for prevention and surveillance. Better prevention strategies (including chemoprevention) could be designed and tested based on the identified targets. And new hypotheses focusing on the genetic and environmental factors associated with prostate cancer risk could be formulated and evaluated.

Body: This is a case-control study of prostate cancer risk. The population of 100 cases and 100 controls under study continues to be recruited at the Georgetown University Hospital. Our recruitment will be also expanded to the Washington Hospital Center and to Veterans Administration Hospital, Washington DC. This will allow us to recruit a large number of African American participants for a comparison of DNA repair differences as a possible cause of the health disparity observed in prostate cancer. The recruitment was originally to be carried out by Dr. Trock. We did organize the recruitment at Georgetown University after Dr. Trock relocated to Johns Hopkins

University, Baltimore. We take advantage of additional funding of Dr. Goldman from the American Cancer Society to accomplish the recruitment for this prostate cancer study.

The recruitment of prostate cancer cases and matched controls was approved by the joint Medstar Research Institute-Georgetown University IRB (see appendix). We developed the alternative case-control recruitment strategy in collaboration with our colleagues from the Department of Urology (Dr. Lynch), Radiation Oncology (Dr. Dritschilo), and Medical Oncology (Dr. Amin). Our preliminary research indicates that Georgetown University, Department of Urology, sees about 150 new prostate cancer cases per year which is sufficient to cover recruitment for the proposed study. Large portion of our effort was devoted to improvement of the case-control study. We adjusted the protocol, included a new compaqrison group (patients with benign prostatic conditions including BPH), created new recruitment procedures and documents, and established collaboration with Dr. Hsing, NCI that forms a basis for expansion of the project to a Washington, DC-wide study of cancer risk in tended to compare African American and Caucasian males.

We have optimized our recruitment strategy and present the improved infrastructure for patient/control recruitment. The appendix shows our newly designed protocol, consent forms for cases and controls, screening form, and questionnaire. In addition, we use an established dietary questionnaire to investigate in greater detail the influence of nutrients on prostate cancer risk. Blood samples and other specimen are collected in collaboration with the GCRC laboratory and sample repository is maintained in collaboration with Biomarker Core at Georgetown University.

The patients for this study are adult residents of the Washington, DC area, ages 18 and older. We enroll all eligible patients that cover the full spectrum of tumor stage and grades. All subjects are briefly informed about the study by the attending physician and referred to a study coordinator. Most patients are seen at the clinic several times prior to treatment and can be enrolled prior to radiation, surgery, or chemotherapy. The coordinator explains the study to the patients, screens for eligibility using a one-page form, obtains informed consent from eligible participants, administers a questionnaire, and assists with collection of specimen (blood, saliva, toenail clipping, and urine) in collaboration with the general clinical research center (GCRC). The personnel of the Histopathology and Tissue Shared Resource collects the tissue not needed for diagnosis at surgery. Flash frozen, OCT embedded, and paraffin embedded tissue is collected in this order as available. Paraffin embedded tissue is also collected for diagnostic purposes by the department of pathology.

Controls are split into two groups: 1. healthy visitors accompanying other patients to the hospital; and 2. patients with non-malignant urologic conditions including benign prostatic hypertrophy (BPH) and prostatitis. This comparison group can be obtained by a simple expansion of the effort to find patients. When we contact biopsied men in the urology clinic, men with positive biopsy are enrolled as cases, men with negative biopsies are enrolled as a comparison group. This is an important comparison group as BPH is not considered to be a pre-cancerous condition and biomarkers that distinguish BPH from early cancer of the prostate better than PSA are needed. This group is valuable comparison group for susceptibility and biomarkers. We exclude spouses and blood relatives to avoid overmatching on genetic factors. The interviewer identifies potential candidates, investigates their willingness to participate, and screens for eligibility using a

one-page form. The interviewer works from a table of enrolled cases and frequency-matches the eligible controls (see below). The candidates are either enrolled immediately or registered in a list of willing eligible controls and join the study at a later time convenient for them or when a match is identified. The interviewer obtains informed consent, questionnaire data (including the dietary questionnaire), and collects 45cc blood sample, saliva, urine, and toenail clipping in collaboration with the GCRC.

The slow growth of prostate cancer and presence of a large percentage of asymptomatic cancer cases in the population presents a challenge to studying prostate cancer. Although the use of PSA and what cut point to use in the clinic is debated, we plan to determine total serum PSA for all recruited controls. We consider serum PSA>2.5 ng/ml as uncertain, in agreement with the latest research. It was shown in population screening of 22,500 participants that total serum PSA is > 4.0 ng/ml in 9% Caucasian and 13% African American males; additional 9% males are positive in the PSA range <2.5-4.0> ng/ml. In our study of 100 controls, PSA screen will therefore detect about 10 controls with PSA>2.5 ng/ml. About 20-40% of the 10 with PSA>2.5 ng/ml, are expected to have cancer at biopsy within next few years. Sufficient controls (approximately 110) will be recruited in order to recruit the 100 controls with PSA<2.5ng/ml as proposed. All assays will be conducted on the larger sample of controls so that they can be included in some analyses. The most restrictive analyses will exclude all controls with PSA > 2.5 ng/ml, with subsequent analyses excluding controls with PSA > 4.0 and PSA > 10.0 ng/ml. Inclusion of the PSA screening as part of the control selection protocol further provides us with the opportunity to explain PSA testing and promote awareness of cancer screening. This is of greatest need in the African American community as the positive predictive value is higher in African American males (45%) compared to Caucasians (25%). All controls with PSA > 2.5 ng/ml will be given referrals to a urologist.

We considered several methods of accruing controls according to the described control selection guidelines. Random-digit phone dialing is likely to have low participation rates because we obtain blood sample for each participant; sibling controls could lead to overmatching on genetic factors; nominated peer controls were not an efficient group - most patients refuse to have their neighbors contacted because they do not want to disclose their disease state. We chose therefore the visitors accompanying other patients. These controls are unbiased with respect to geography and socioeconomic status as they came to the hospital from the same referral area as the cancer cases. The subjects usually accompany a person to the hospital repeatedly, are motivated to participate, are easily contacted as they wait in the clinic, and typically do not make a special trip to the clinic for the study. It is a nonrandom subset, but was shown to be an excellent comparison group in several large studies.

Controls are matched to HNSCC cases on age (5 years), and race. It is important to match on these factors so that hypothesis testing is not compromised by severe imbalances in subject characteristics. We use frequency-matching whereby the proportions of cases and controls in each 5-year age group within each race category are held as closely similar as possible. In practice, this is accomplished by tabulating patient frequencies (updated monthly). This table shows the categories of race and age that were underrepresented among previously recruited controls, which helps the interviewer to choose an appropriate control. We have found that monthly adjustment of the recruitment

tables allows us to control emerging characteristics of the case and control groups and to adjust recruitment where needed.

Subjects are interviewed face-to-face by a trained interviewer. In special cases the interview can be conducted over-the-phone or mailed in (for patients with speech problems). The questionnaire asks about demographic information, reproductive history, tobacco use, alcohol consumption, general medical history and family history, occupational exposures, residential history, exercise, and education. Every newly completed questionnaire is checked by a supervisor; together they identify and correct any errors or inconsistencies prior to data entry. Double data entry is performed with automated range and consistency checks (in Microsoft Access). The files are protected by passwords and encryption.

An experienced phlebotomist collects the blood samples at each recruitment site. Each subject provides a single 45 cc blood sample drawn into pre-labeled vacutainer glass tubes. Urine, toenail, and saliva are collected according to standard procedures and frozen for future studies as needed. The surgical tissue not needed for diagnosis is collected at surgery by the personnel of the Histopathology and Tissue Shared Resource. Flash frozen, OCT embedded and paraffin embedded tissue is collected in this order as available. The blood tubes are immediately refrigerated and delivered on ice within 6 hours to the GCRC core facility at Georgetown University for processing. Case-control status is masked to the lab personnel since the blood collection tubes show only a numeric study ID and sample collection date. We collect two red top tubes (no preservative), two green top tubes (sodium heparin), and one purple top tube (EDTA). Each sample is centrifuged and the blood components are separated into serum, clot, buffy coat, and plasma within 2 hours of reception. The blood components are divided into aliquots of 0.5-to-1 ml each, frozen at -80°C and stored in a centrally monitored freezer facility.

We have recruited 21 cases and 20 controls **(Table 1)** and obtained samples of serum, plasma, buffy coat, mouth wash, urine, and toenail clipping for each participant.

Table 1.	**Cases n=51**		**Controls n=42**	
	(%)		**(%)**	
AGE				
less than 60	27		34	
60 – 70	46		47	
over 70	27		19	
RACE				
White	84		86	
Black	16		14	
Gleason Score				
<= 6	58			
7-10	42			
STAGE (%)	**PSA Cases (%)**		**PSA Control (%)**	
T1 36	<=4	9	<=4	100
T2 55	>4	91	>4	0
T3 9				

These samples constitute a repository of samples for prostate cancer biomarker research and serve for the testing of mutagen sensitivity and other endpoints in this study as described below. Dr. Goldman's laboratory at Georgetown University relocated to renovated space in the Lombardi Cancer Center. The new space contains all the

equipment necessary for the proposed research including refrigerated centrifuges, incubators and tissue culture hoods, and microscopes including a fluorescent microscope with a comet imaging system. We also benefit from a nearby high throughput genotyping facility equipped with five 96-well PCR machines, 2 tetrad PCR machines (4 blocks X 384 wells), a Perkin-Elmer 377 sequencer, ABI 7900HT, Amersham Megabase 96 capillary sequencer, Transgenomic Wave dHPLC, Quiagen M48 Biorobot, Multimek robotics, Affymetrix microarray scanner with 2 hypbridization sytems, 96 well format automated sequencer, a Perkin-Elmer 770 flourescent DNA analyzer, and a Biorepository system with a server. The laboratory is CLIA certified. There is a centrally monitored storage facility with –80°C freezers. The established recruitment and optimized sample processing in the new laboratory allows rapid expansion of the study.

Aim 1. Determine whether high mutagen sensitivity is associated with high prostate cancer risk.

After departure of Michelle Xia Ma following maternity leave, the work is currently continued by Daniel Saha and Alexandra Dakic. They were trained in the mutagen sensitivity procedure and continue development of the comet assay for quantification of DNA damage and repair. We focused on the training of new personnel, optimization of comet assay, and optimization of the case-control study procedures.

We have analyzed mutagen sensitivity in 21 cases and 20 matched controls. For each person, a 62 hour culture of fresh whole blood collected in a green top (sodium heparin) vacutainer tube is established and the lymphocytes are stimulated with phytohemagglutinine. The cells are exposed for 5 hours to bleomycin, fixed, and microscopic slides with chromosomal spreads are stained with Giemsa stain as described previously (20). The results show that mean breaks in cases (mean 0.88 SD 0.32) are higher than in controls (mean 0.74 SD 0.34), but the result is not statistically significant (Table 2) .

Table 2.

ID	Status	Breaks/cell	ID	Status	Breaks/cell
11591	case	0.5			
11592	case	0.88	**11742**	control	0.4
11662	case	0.36	**11906**	control	0.74
11852	case	0.78	**13699**	control	0.92
11910	case	0.56	**13701**	control	1.76
11940	case	0.66	**13715**	control	1.16
11943	case	0.96	**13717**	control	0.9
11996	case	0.92	**13721**	control	0.78
12085	case	1.1	**13725**	control	0.58
12248	case	0.56	**13727**	control	0.42
12350	case	1.04	**13728**	control	0.6
12369	case	0.76	**13730**	control	0.58
13471	case	1.1	**13731**	control	0.7
13654	case	1.76	**13732**	control	0.44
13734	case	1	**13733**	control	0.9
13742	case	1.1	**13739**	control	0.66
13748	case	0.52	**13741**	control	1.12

13755	case	1.32	**13759**	control	0.88
13756	case	0.68	**13770**	control	0.42
13761	case	0.88	**13772**	control	0.38
13782	case	1.02	**13741**	control	0.42
Mean		**0.88**	**Mean**		**0.74**
St Dev		**0.32**	**St Dev**		**0.34**

The sample size is not large enough yet to expect significant differences. The completed recruitment of 100 cases and controls in the 3rd year of the study will provide sufficient number of subjects for the hypothesis testing.

In addition to the mutagen sensitivity, we began evaluating comet assay as an alternative protocol for DNA damage/repair. This assay is an increasingly popular tool for human biomonitoring (1) with the potential to identify cancer-prone individuals in the general population (2). Both comet assay and mutagen sensitivity measure DNA damage in short-term cultured human lymphocytes exposed to bleomycin (or other mutagens). While mutagen sensitivity is an established tool in population-based studies of cancer risk and was associated with increased risk of glioma, lung, colon, hepatocellular, and HN carcinoma (1), comet assay was used only recently in three pilot studies of breast, cervical, and lung cancer (1). The largest of the studies examined 100 lung cancer patients and 110 controls using comet assay and found correlation of cancer risk with increased DNA damage (OR 4.2; CI 2.2-7.4) (21). In addition, DNA repair (measured as rate of damage disappearance) was an independent predictor of risk (OR 2.1; CI 1.1-4.0). Comet assay has several advantages compared to mutagen sensitivity: 1. Comet assay provides independent measures of DNA damage and repair; 2. Comet assay is reported to have higher throughput, better reproducibility and quantification, and lower cost per assay; and 4. Comet assay uses small sample size (also called SCGE, single cell gel electrophoresis assay) (2). Our preliminary results are encouraging.

Our first experiments follow published experimental settings with minor modifications (21). Agarose slides for this procedure were prepared as follows:

1) Coat microscope slide with normal melting point agarose (NMPA), solidify on ice for 5 min
2) Add cell suspension to low melting point agarose (LMPA) and form a layer of cell suspension on the NMPA coated slide
3) Dip the preparation in cold alkaline (pH>13) lysing solution (4°C) for 3 hours
4) Transfer the preparations from lysing solution to alkaline electrophoresis buffer for 40 minutes to unwind DNA
5) Separate DNA for 25 minutes at 4°C by alkaline electrophoresis using 0.92 V/cm and 300 mA current
6) Fix preparations with methanol, wash with distilled water
7) Stain with 0.01% ethidium bromide
8) Acquire 50 cell images per experiment (2 slides per experiment) using a fluorescent microscope with CDD camera (Olympus) and evaluate average fluorescent intensity in the head (intact nuclear DNA) and tail (damaged DNA) using comet imaging software (Loats Inc., Gaithersburg, MD). This imaging system was purchased by Lombardi Cancer Center and installed in our laboratory.

Lymphocytes from short term culture in the presence of PHA (62 hours) and IL2 (24 hours) were treated with 60 μg/ml bleomycin solution. Control samples were treated with the same volume of medium. After 30 min the samples were washed with fresh medium and subjected immediately to alkaline lysis (analysis of DNA damage) or incubated in fresh medium for 8 and 15 min at 37°C before alkaline lysis (analysis of DNA damage repair). The experiment was done on three independent cultures from the same blood sample and each performed in duplicate for a total of 6 measurements at each dose/time (Table 3).

Table 3. **Reproducibility of Bleomycin Induced Comets**

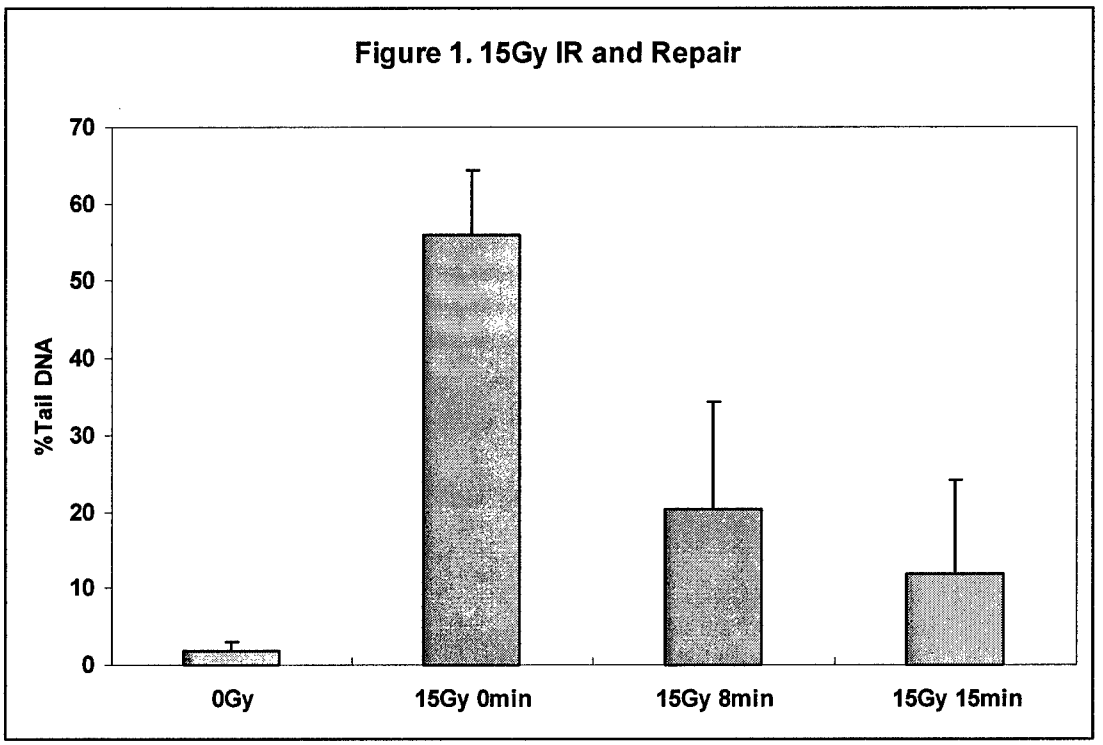
Experiment	0 ug/ml	60ug/ml 0min	60ug/ml 8min	60ug/ml 15min
1	0.964	90.023	77.01101124	31.513
2	0.163	92.257	57.45676768	35.2921
3	2.53	82.6808	31.4653	22.4742
4	5.58	76.0992	46.7498	18.5163
5	1.2675	38.998	13.1558427	1.355384615
6	1.3635	33.717	24.8144	3.1712
Mean	1.98	68.96	41.78	18.72
SD	1.92	25.94	23.35	14.11

This experiments (and several subsequent repeats with modifications) revealed that the measurement is not sufficiently reproducible between cultures to allow screening of samples in a population study. This prompted us to test ionizing radiation, which is known to yield the best results in terms of dosing and reproducibility. This experiment was done initially using 0-2 Gy of radiation, but even the highest dose resulted in only minor increase in % tail DNA. As we are interested in the quantification of DNA repair, this dose was not sufficient and we increased the dose to 5-15 Gy subsequently. We did also modify the electrophoretic conditions by increasing electrophoresis time to 40 minutes. With these conditions, we achieved better reproducibility of the experiments as exemplified by the presented exposure to 15 Gy (Table 4).

Table 4. **Reproducibility of IR induced Comets**

Experiment	0Gy	15Gy 0min	15Gy 8min	15Gy 15min
1	2.78	54.35	12.51	8.89
2	3.33	46.28	18.41	8.38
3	0.90	67.21	48.77	36.74
4	0.36	55.61	14.82	5.16
5	1.75	47.32	13.37	6.42
6	1.93	64.47	14.64	5.64
Mean	1.84	55.87	20.42	11.87
SD	1.11	8.60	14.03	12.27

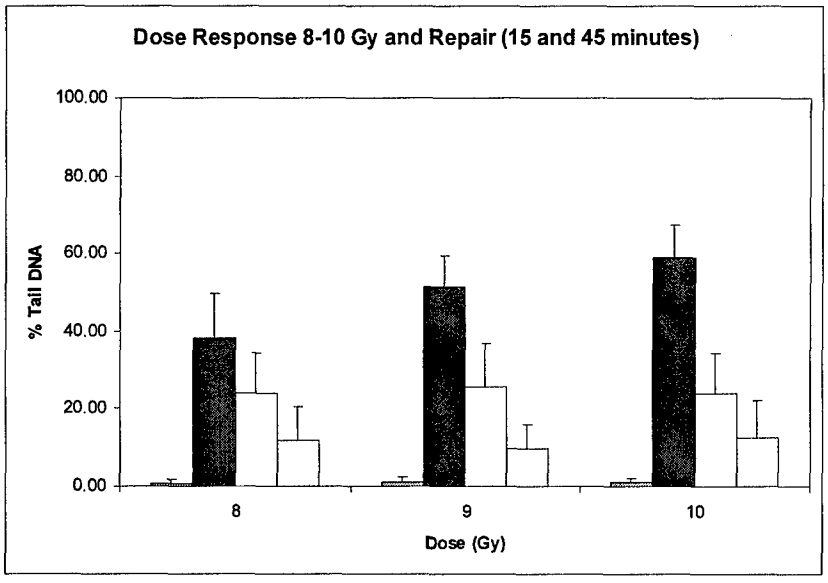
The mean and standard deviation are summarized in the in **Figure 1.**



We are investigating currently what percentage of cells undergoes apoptosis following the exposure to ionizing radiation, what is the kinetic of DNA repair at longer time points, and the reasons for the higher variability of the assays using bleomycin as the damaging agent. It was suggested in the literature that the repair of DNA damage following radiation is biphasic with a relatively fast repair of single strand breaks (within 15 minutes) and a slower repair of the residual damage, presumably double strand breaks, with a kinetic of hours. We hope to incorporate the optimized protocol into the population study and compare the repair phenotypes measured by mutagen sensitivity and comet assay.

Upgrade of the fluorescent microscope and software for scoring of comets (LOATS Associates, Westminster, MD) and further adjustment of the experimental protocol adjusted the experimental protocol to use of lower doses and longer time point for DNA repair. Here I present comparison of dose response to 8 to 10 Gy of radiation and repair at 15 and 45 minute time point (Fig. 2). The initial damage undergoes fast repair (within 15 minutes) and continues with a slow phase that is quantified at 45 minutes. We will examine patients under 9 Gy exposure at these time-points; we believe that all three time points provide independent information (damage, fast repair, and slow repair).

Figure 2.



Legend:
Blue series: unexposed
Red series: 0 minutes
Yellow series: 15 minutes
Green series: 45 minutes

Aim 2. Determine whether low apoptotic response is associated with increased prostate cancer risk.

We did perform Anexin V assay for phosphatidylserine flipping based on flow cytometry on 10 cases and 10 control samples of short term cultured lymphocytes (Table 5).

Table 5. **Apoptosis following exposure to bleomycin**

	0ug/ml	20ug/ml	60ug/ml		0ug/ml	20ug/ml	60ug/ml
Control	12.92	31.38	38.74	case	10.13	26.32	39.76
Control	11.55	25.05	33.18	case	29.06	12.50	36.25
Control	9.04	19.90	30.20	case	35.01	44.96	47.22
Control	25.07	34.85	40.37	case	82.99	87.09	85.07
Control	11.58	29.77	40.29	case	20.82	37.72	39.32
Control	7.00	19.84	36.44	case	19.10	28.09	37.68
Control	11.96	25.04	37.54	case	18.50	25.67	41.42
Control	64.43	63.37	63.49	case	35.68	53.52	61.69
Control	33.96	44.19	49.92	case	36.39	50.83	53.98
Control	20.13	38.42	51.23	case	17.90	33.06	36.71
Mean	20.76	33.18	42.14	Mean	30.56	39.98	47.91
SD	17.43	13.18	9.96	SD	20.50	20.78	15.48

We did previously modify the tissue culture procedure by addition of IL2 following the culture in the presence of PHA in order to decrease variability of the assay. This worked reasonably well when performed on volunteer blood, but less well in the study as can be seen in Table 6. There are a number of samples with high background of Anexin V staining, especially in cancer cases. This can be due to the unhealthy lifestyle, treatment with antibiotics, or other unknown reasons. It is also possible that the treatment with bleomycin is not sufficiently reproducible in this experimental setting even though we take care to use the same lot of reagent and aliquot the reagent as carefully as possible. We are currently evaluating the option to perform the apoptosis measurements on cells

exposed to ionizing radiation and we are further optimizing the tissue culture protocol to eliminate the observed variability.

The exposure of lymphocytes to 0, 5, and 10 Gy of radiation led to small increase in apoptosis at 19 hour after exposure. We observe minimal effect of radiation immediately after exposure based on Anexin 5 staining. After 19 hours, percentage of cells in the first quadrant (FCS1) decreases with dose and quandrants 2 (FCS2, early apoptosis) and 3 (FCS3, late apoptosis) increase with dose. Table shows three individual experiments with mean and standard deviation.

Table 6.

Time (h)	Dose(Gy)	FCS1 (%)	FCS1 (%)	FCS1 (%)	**Mean1 FCS1**	**Std. Dev1 FCS1**
	0	77.17	89.66	95.20	**87.34**	**9.24**
0	5	74.86	90.04	94.66	**86.52**	**10.36**
	10	74.27	88.68	80.85	**81.27**	**7.21**
	0	78.36	83.72	73.98	**78.69**	**4.88**
19	5	70.60	75.20	54.22	**66.67**	**11.03**
	10	60.92	68.34	49.47	**59.58**	**9.51**
Time (h)	Dose(Gy)	FCS2 (%)	FCS2 (%)	FCS2 (%)	**Mean1 FCS2**	**Std. Dev1 FCS2**
	0	17.44	6.92	2.37	**8.91**	**7.73**
0	5	19.17	6.48	3.44	**9.70**	**8.34**
	10	19.84	7.22	12.60	**13.22**	**6.33**
	0	15.50	11.94	9.16	**12.20**	**3.18**
19	5	19.76	16.41	25.81	**20.66**	**4.76**
	10	26.16	21.06	29.15	**25.46**	**4.09**
Time (h)	Dose(Gy)	FCS3 (%)	FCS3 (%)	FCS3 (%)	**Mean1 FCS3**	**Std. Dev1 FCS3**
	0	4.05	3.09	1.28	**2.81**	**1.41**
0	5	5.10	3.17	1.86	**3.38**	**1.63**
	10	5.10	3.67	5.16	**4.64**	**0.84**
	0	4.98	3.82	16.59	**8.46**	**7.06**
19	5	8.04	7.42	19.52	**11.66**	**6.81**
	10	11.27	9.72	20.76	**13.92**	**5.98**

Aim 3. Determine whether the 'at risk' genetic variants of *OGG1* and *XRCC1* are risk factors for prostate cancer.

The testing of single nucleotide polymorphisms is a straightforward application of established procedures. Both the OGG1 and XRCC1 genotyping protocols were tested on pedigree DNA and are fully prepared for the population testing. In addition, we have access to a newly established High Throughput Genotyping Facility at the Lombardi Cancer Center which will allow us to screen a number of relevant polymorphisms in a very short time.

Key Research Accomplishments

1. The infrastructure for recruitment of cases and controls at Georgetown University Hospital was improved. We have obtained questionnaire data and biological specimen form 51 cases and 42 matched controls. Tumor tissue was obtained for 2 cases so far.
2. The preparation of mutagen sensitivity slides was performed for all the participants. We evaluated so far 21 cases and 20 controls and scoring of additional samples will follow full training of the laboratory personnel. The current result shows that men breaks are higher in cases (mean 0.88 SD 0.32) than in controls (mean 0.74 SD 0.34).
3. We did develop a complementary procedure for quantification of DNA repair capacity based on comet assay. This measurement was optimized to measure slow and fast repair kinetic at 9 Gy exposure. This assay will be tested on a pilot sample of cases/controls from our study.
4. Lombardi Cancer Center created a high throughput genotyping facility directed by Dr. Shields. This center will facilitate rapid analysis of any number of polymorphisms that we will study as the recruitment reaches the established goal of 100 cases and matched controls.

Reportable Outcomes

None. The study will provide reportable results as the recruitment reaches a critical mass. We hope to report also a paper describing the comet assay and apoptosis in cultured peripheral blood lymphocytes.

Conclusions

The study progresses slower than expected due to the development of a new recruitment strategy for cases and controls. We have established the recruitment procedures, sample collection, processing, repository, and data management. This is a substantial effort that is made possible by generous support from the Lombardi Cancer Center through the GCRC, Biomarker Core, Histopathology and Tissue Core, and additional funding of Dr. Goldman form the American Cancer Society. We carried out mutagen sensitivity experiments on all received blood samples and also continue to optimize comet assay as an additional measure of DNA repair and response to genotoxic stress. Genotyping assays can be easily accomplished when the recruitment reaches the proposed goal of 100 cases and control. We have optimized all the genotyping assays and have access to a newly established High Throughput Genotyping Facility at the Lombardi Cancer Center which will allow us to screen a number of relevant polymorphisms in a very short time. We expect to complete the evaluation of mutagen sensitivity for the study population and

to complete comet assay for at least half of the population by the completion of the extension period. The current recruitment procedures and study design will be fully tested and expended in subsequent studies.

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Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

Informed Consent for Clinical Research (cases)

MedStar Research Institute/Georgetown Medical Center

INSTITUTION: GUMC + WHC

INTRODUCTION

We invite you to take part in a research study. The study is called 'Molecular Epidemiology of Prostate Cancer'. Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary;

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;

(c) You may withdraw from the study at any time without any of the benefits you would have received normally being limited or taken away.

The nature of the study, the benefits, risks, discomforts and other information about the study is discussed below. Any new information discovered, at any place during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask the staff members any questions you have about this study and the staff members will explain the questions to you. The investigator (person in charge of this research study) is Dr. Radoslav Goldman. The research is being sponsored by the Department of Defense. The Department of Defense is called the sponsor and the Georgetown University is being paid by the Department of Defense to conduct this study with Dr. Radoslav Goldman as the primary investigator.

WHY IS THE STUDY BEING DONE?

You are being asked to participate in this study because you are suspected of having prostate cancer or have prostate cancer. Your prostate tumor, blood and other samples may show us how cancer develops and what are the factors that helped increase the cancer risk.

The purpose of this study is to learn about the natural history of prostate cancer and its causes and treatments. This research is being done because the causes of prostate cancer are not well understood at present. The purpose of this research is to see how someone's ability to respond to genetic damage

modifies risk of prostate cancer. We will test how your ability to repair damaged DNA and eliminate cells that did not repair the damage modifies prostate cancer risk.

We will examine your blood, cheek samples, saliva, nail clippings and urine to see if tests for your response to chemical exposure can help us predict who might be at greater risk of prostate cancer. If you are going to have surgery, or had surgery, or if you are going to have a biopsy or had a biopsy, we will use samples of tumor tissue, as well as adjacent normal tissue, to determine whether markers in the tissue suggest how the cancer developed. The specimen will not be used for diagnostic purposes or for purposes related to your medical care. That is, the experiments done on these samples will not be used for decisions about your personal risk of prostate cancer, your treatment or your prognosis. These specimens will be available to qualified medical researchers for scientific studies that have been approved by the Principal Investigator, listed above, and an oversight committee. Researchers who receive these samples will not have access to your name or other identification information.

If you wish, you will be given the opportunity to identify friends living in your geographical area to be controls in the study. This would help us to identify a group of controls subjects without prostate cancer. We hope that this research can lead to the discovery of new tests for cancer risk, including genetic tests.

All men older than 18 years of age at all stages of presentation are eligible to participate in this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 600 people (300 patients and 300 controls) will take part in this study and will be recruited at Washington Hospital Center and Georgetown University Medical Center. Participants in the study are referred to as "subjects".

WHAT IS INVOLVED IN THE STUDY?

Upon reviewing and signing this informed consent, you will begin the study. We will ask you questions using a form that will take about an hour to finish. If you do not want to do the whole questionnaire at the time you give blood, we can do only one part lasting about 15 minutes and then we will contact you later to finish the study. This research will be conducted on an experimental basis only, and you will not be provided with any information about your test results.

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

If you take part in this study, you will have the following tests and procedures

1. Upon reviewing and signing this informed consent, you will begin the study.
2. Undergo an in person interview lasting about one hour administered by a trained interviewer.
3. Provide a blood sample that is about 3 tablespoons.
4. Provide a urine specimen.
5. Provide two cheek swab samples.
6. Provide saliva
7. Provide nail clipping.
8. Allow us to use the unneeded portion of your prostate tissue, as well as a small sample of adjacent normal tissue for research purposes.

HOW LONG WILL I BE IN THE STUDY?

We expect that your participation in the study will take an extra hour in addition to your scheduled examination. The study is completed after you finish your questionnaire and donate your blood, urine, nail, cheek sample, saliva and tissue from surgery/biopsy not needed for diagnostic purposes. However, if you agree below, we may call you in the future for additional information and/or sample collection. We will use your sample for different tests as described above and as new hypotheses develop for as long as it lasts and is useful for our testing. If the sample is no longer useful, it will be destroyed. However, you can request that your blood, cheek, saliva, nail, urine and prostate tissues be destroyed at any time. To have your samples destroyed, you can contact Dr. Goldman at 202-687 9868.

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

In the future, it might be necessary to contact you for further information or an additional blood sample (or other type of biological sample). If this is okay, please indicate below. You can refuse to do so now or later. Please check and initial below:

I ____may ____may not be contacted in the future for further information or biological samples.

_____ Sign your initials here.

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

WHAT ARE THE RISKS OF THE STUDY?

There is a very slight chance of a bruise or an infection from the blood draw, but we use only trained medical technicians to draw your blood and they will use the best available precautions. Another possible risk is that your genetic information might be obtained by persons from outside the study. We will minimize this chance by maintaining the confidentiality of your test results and study records at all times (see below). For more information about risks and side effects, ask the research staff or contact Radoslav Goldman at 202-687- 9868.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there is no direct medical benefit to you. We hope the information learned from this study will benefit others in the future.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your personal information to the extent allowed by law. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. Organizations that may request, inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as: Department of Defense, Food and Drug Administration, MedStar Research Institute, Georgetown University, and Institutional Review Board (IRB).

We will store your tissue, blood, cheek, saliva, nail and urine samples, or genetic material prepared from your blood, urine, cheek, nail or prostate tissue, in a secure room with restricted access. Only people working on this research project can work on your sample. Because we want to protect your confidentiality, your samples will have only a number on the tube and will not have your name or other identifier information.

We will protect your genetic and other testing results. We will control access to the computer files that hold this information. Access to the computer files can only be obtained through multiple passwords. Only authorized study personnel can link your sample to you. This information will not be released to anyone. "Anyone" includes you, your family, your doctor, your insurance company, or your employer. This is because the research is at a very early stage and we would not be able to tell you what your results mean. This information will not be included in any medical records.

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that the Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

WHAT ARE THE COSTS?

There is no cost to participate in the study.

You should not expect any one to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

RESEARCH RELATED INJURY

The Department of Defense is partially funding this research. Should you be injured as a direct result of participating in this research, you will be provided medical care at no cost to you. You will not receive any injury compensation, only medical care. Your insurance company will be billed, but you will not be liable for any costs not covered by your insurance. Additional information on this subject

may be obtained from the Office of the Medical Director, Georgetown University Hospital at (202) 784-3011.

You *will not* be paid for participating in this study.

COMMERCIAL INTEREST

On rare occasions, laboratory research on human specimens results in discoveries that are the basis for new research products or diagnostic and therapeutic methods. It is the policy of Georgetown University Medical Center, MedStar, Inc., and their affiliates not to compensate you for any future financial claim to your tissues for research and development for commercial and noncommercial purposes. No funds are available or will be paid by the MedStar Research Institute, MedStar Health or Georgetown University to repay you in case of injury.

_____ I understand that I will not receive financial compensation for my biological samples at any time. (sign initials here)

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you request, the link between your name and the study results will be destroyed. Also, your biological samples will be discarded at your request. However, the results of any finished analysis and or published result will be kept to preserve the validity of the study. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally.

We will not provide you with any of the results we obtain from your biological samples.

We will tell you about new information that may affect your health, welfare, or participation in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, problems, unexpected physical or psychological discomforts or injuries related to the study, contact day or night the research doctor, Radoslav Goldman at 202-687 9868. If you would like to write to him, please send mail to: Radoslav Goldman,

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

Georgetown University, 3970 Reservoir Road NW, Research Building W309A, Washington DC 20057.

If you are a participant at Washington Hospital Center and have questions about your rights as a research participant, contact the MedStar Research Institute. Direct your questions to Dr. Barbara Howard at Medstar Research Institute:

MedStar Research Institute
6495 New Hampshire Ave., Suite 201
Hyattsville, MD 20783
Tel: (301) 853-7532
Pager: 1-888-663-6842

If you are a participant at Georgetown University Medical Center and have questions about your rights as a research participant, contact the Georgetown University IRB Office. Direct your questions to:

Ms. Laura Miller, Executive Officer, Institutional Review Board at:
Address: Georgetown University Medical Center
3900 Reservoir Road, N.W.
NE 105 Med-Dent
Washington, D.C. 20007
Telephone: (202) 687-1506

SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individuals satisfaction.

_____ _____

Signature of person obtaining the consent Date

I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my

decision. This withdrawal will not in any way effect my future treatment or medical management. I agree to cooperate with Dr. Radoslav Goldman and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____

_____

Name and Permanent Address of Subject (Printed)

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

_____ _____

Principal Investigator (if not person obtaining consent) Date

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

Follow up Sample Acquisition Consent

As a continuation of the study in which I enrolled on _____ (date), I agree to provide a set of biological samples including urine, blood (about 3 tablespoons), cheek cells, and saliva and to answer questions about my medical history. In case I undergo surgery to remove a tumor, I agree to donate the unneeded portion of my head and neck tissue as well as adjacent normal tissue removed at surgery for research purposes. I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way effect my future treatment or medical management. I agree to cooperate with Dr. Radoslav Goldman and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms related to the research study.

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

_____ _____

Principal Investigator (if not person obtaining consent) Date

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

Informed Consent for Clinical Research (controls)

MedStar Research Institute/Georgetown Medical Center

INSTITUTION: GUMC + WHC

INTRODUCTION

We invite you to take part in a research study. The study is called 'Molecular Epidemiology of Prostate Cancer'. Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary;

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;

(c) You may withdraw from the study at any time without any of the benefits you would have received normally being limited or taken away.

The nature of the study, the benefits, risks, discomforts and other information about the study is discussed below. Any new information discovered, at any place during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask the staff members any questions you have about this study and the staff members will explain the questions to you. The investigator (person in charge of this research study) is Dr. Radoslav Goldman. The research is being sponsored by the Department of Defense. The Department of Defense is called the sponsor and the Georgetown University is being paid by the Department of Defense to conduct this study with Dr. Radoslav Goldman as the primary investigator.

WHY IS THE STUDY BEING DONE?

You are being asked to participate in this study because a comparison group free of prostate cancer is needed to evaluate the results. Your blood and other samples may show us how cancer develops and what the factors are that help increase cancer risk.

The purpose of this study is to learn about the natural history of prostate cancer and its causes and treatments. This research is being done because the causes of prostate cancer are not well understood at present. The purpose of this research is to see how someone's ability to respond to genetic damage

modifies risk of prostate cancer. We will test how your ability to repair damaged DNA and eliminate cells that did not repair the damage modifies prostate cancer risk.

We will examine your blood, cheek swabs, saliva, nail clippings and urine to see if tests for your response to chemical exposure can help us predict who might be at greater risk of prostate cancer. The specimens will not be used for diagnostic purposes or for purposes related to your medical care. That is, the experiments done on these samples will not be used for decisions about your personal risk of prostate cancer. These specimens will be available to qualified medical researchers for scientific studies that have been approved by the Principal Investigator, listed above, and an oversight committee. Researchers who receive these samples will not have access to your name or other identification information. We hope that this research can lead to the discovery of new tests for cancer risk, including genetic tests.

Men older than 18 years of age free of prostate cancer are eligible to participate in this study. To minimize the possibility that you have undetected prostate cancer, we will perform a test for prostate specific antigen (PSA) on a portion of your blood sample free of charge to you. If your test shows a PSA value greater than 2.5ng/ml, a follow up examination by a doctor will be recommended.

_____ (please initial) I agree to have my PSA level tested .

_____ (please initial) I agree to have my physician notified at the following address if the PSA level is elevated. If you do not have a physician, we recommend that you contact one in case the PSA level is elevated.

Physician's name: _____

Address:_____

_____

_____

Phone:_____ Fax:_____

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 600 people (300 patients and 300 controls) will take part in this study and will be recruited at Washington Hospital Center and Georgetown University Medical Center. Participants in the study are referred to as "subjects".

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

WHAT IS INVOLVED IN THE STUDY?

Upon reviewing and signing this informed consent, you will begin the study. We will ask you questions using a form that will take about an hour to finish. If you do not want to do the whole questionnaire at the time you give blood, we can do only one part lasting about 15 minutes and then we will contact you later to finish the study. Your blood, cheek cells, saliva, nail tissue, and urine will be tested for their response to chemical exposure, in order to identify tests that may predict cancer risk. This research will be conducted on an experimental basis only, and apart from your PSA test results, you will not be provided with any other information.

If you take part in this study, you will have the following tests and procedures:

1. Upon reviewing and signing this informed consent, you will begin the study.
2. Undergo an in person interview lasting about one hour administered by a trained interviewer.
3. Provide a blood sample that is about 3 tablespoons. One of the samples will be tested to determine your PSA level.
4. Provide a urine specimen.
5. Provide two cheek swab samples.
6. Provide saliva.
7. Provide nail clippings.

HOW LONG WILL I BE IN THE STUDY?

We expect that your participation in the study will take about an hour. The study is completed after you complete your questionnaire and donate your blood, urine, nail clippings, saliva and a cheek sample. However, if you agree below, we may call you in the future for additional information and/or sample collection. We will use your sample for different tests as described above and as new hypotheses develop for as long as it lasts and is useful for our testing. If the sample is no longer useful, it will be destroyed. However, you can request that your blood, cheek cells, saliva, nail tissue, and urine be destroyed at any time. To have your samples destroyed, you can contact Dr. Goldman at 202-687-9868.

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

In the future, it might be necessary to contact you for further information or an additional blood sample (or other type of biological sample). If this is okay, please indicate below. You can refuse to do so now or later. Please check and initial below:

I ____may ____may not be contacted in the future for further information or biological samples.

_____ Sign your initials here.

WHAT ARE THE RISKS OF THE STUDY?

There is a very slight chance of a bruise or an infection from the blood draw, but we use only trained medical technicians to draw your blood and they will use the best available precautions. Another possible risk is that your genetic information might be obtained by persons outside the study. We will minimize this chance by maintaining the confidentiality of your test results and study records at all times (see below).
For more information about risks and side effects, ask the research staff or contact Radoslav Goldman at 202-687 9868.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there is no direct medical benefit to you. We hope the information learned from this study will benefit others in the future.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your personal information to the extent allowed by law. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. Organizations that may request, inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as: Department of Defense, Food and Drug Administration, MedStar Research Institute, Georgetown University, and Institutional Review Board (IRB).
We will store your blood, cheek, saliva, nail and urine samples, or genetic material prepared from your blood, urine, cheek, saliva and nail in a secure room with restricted access. Only people working on this research project can work on your samples. Because we want to protect your confidentiality, your samples will have only a number on the tube and will not have your name or other identifier information.

We will protect your genetic and other testing results. We will control access to the computer files that hold this information. Access to the computer files can only be obtained through multiple passwords. Only authorized study personnel can link your sample to you. This information will not be released to anyone. "Anyone" includes you, your family, your doctor, your insurance company, or your employer. This is because the research is at a very early stage and we would not be able to tell you what your results mean. This information will not be included in any medical records.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that the Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

WHAT ARE THE COSTS?

There is no cost to participate in the study
You should not expect any one to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

RESEARCH RELATED INJURY

The Department of Defense is partially funding this research. Should you be injured as a direct result of participating in this research, you will be provided medical care at no cost to you. You will not receive any injury compensation, only medical care. Your insurance company will be billed, but you will not be liable for any costs not covered by your insurance. Additional information on this subject may be obtained from the Office of the Medical Director, Georgetown University Hospital at (202) 784-3011.

You *will not* be paid for participating in this study.

COMMERCIAL INTEREST

On rare occasions, laboratory research on human specimens results in discoveries that are the basis for new research products or diagnostic and therapeutic methods. It is the policy of Georgetown University Medical Center, MedStar, Inc., and their affiliates not to compensate you for any future financial claim to your tissues for research and development for commercial and noncommercial purposes. No funds are available or will be paid by the MedStar Research Institute, MedStar Health or Georgetown University to repay you in case of injury.
I understand that I will not receive financial compensation for my biological samples at any time.
_____(sign initials here)

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you request, the link between your name and the study results will be destroyed. Also, your biological samples will be discarded at your request. However, the results of any finished analysis and or published result will be kept to preserve the validity of the study. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally.
We will tell you about new information that may affect your health, welfare, or participation in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, problems, unexpected physical or psychological discomforts or injuries related to the study, contact day or night the research doctor, Radoslav Goldman at 202-687-9868. If you would like to write to him, please send mail to: Radoslav Goldman, Georgetown University, 3970 Reservoir Road NW, Research Building W309A, Washington DC 20057.

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

If you are a participant at Washington Hospital Center and have questions about your rights as a research participant, contact the MedStar Research Institute. Direct your questions to Dr. Barbara Howard at Medstar Research Institute:

MedStar Research Institute
6495 New Hampshire Ave., Suite 201
Hyattsville, MD 20783
Tel: (301) 853-7532
Pager: 1-888-663-6842

Or

If you are a participant at Georgetown University Medical Center and have questions about your rights as a research participant, contact the Georgetown University IRB Office. Direct your questions to:

Ms. Laura Miller, Executive Officer, Institutional Review Board at:
Address: Georgetown University Medical Center Telephone: (202) 687-1506
3900 Reservoir Road, N.W.
NE 105 Med-Dent
Washington, D.C. 20007

SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____

Signature of person obtaining the consent Date

I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way effect my future treatment or medical management. I

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

agree to cooperate with Dr. Radoslav Goldman and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____

_____

Printed name and permanent address of subject.

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

_____ _____

Principal Investigator (if not person obtaining consent) Date

Study number:_ Principal Investigator (s): Radoslav Goldman
Title Molecular Epidemiology of Prostate Cancer

Follow up Sample Acquisition Consent

As a continuation of the study in which I enrolled on _____ (date), I agree to provide a set of biological samples including urine, blood (about 3 tablespoons), cheek cells, and saliva and to answer questions about my medical history. I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way effect my future treatment or medical management. I agree to cooperate with Dr. Radoslav Goldman and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms related to the research study.

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date

_____ _____

Principal Investigator (if not person obtaining consent) Date

MedStar Research Institute-
Georgetown University Oncology
Institutional Review Board

IRB Number: _____

MedStar Research Institute-Georgetown University Oncology Institutional Review Board Application (Protocol) IRB Review (AB-1)

Section One: Application Information

Principal Investigator	Radoslav Goldman, Ph.D.
Department	Oncology
Title	Assistant Professor
Phone/Pager: 202-687 9868	**Fax:** 202-687 1988
E-mail address:rg26@georgetown.edu	
Mailing Address: Georgetown University, Lombardi Cancer Center, LL (S) Level, Room 183, 3800 Reservoir Rd. NW, Washington DC 20057	
Co-Investigator: Christopher Loffredo, Department of Oncology	
Title: Assistant Professor	
Phone/Pager: 202-6873758	**Fax:** 202-7843034
Email address: cal9@georgetown.edu	
Mailing Address: Georgetown University, S-153, 3800 Reservoir Rd. NW, Washington DC 20057	
Study Coordinator (member of faculty or administrative official) Alexandra Schopf	

Title of Project	**Purpose of Project (one or two sentences)**
Molecular Epidemiology of Prostate Cancer	This study has two goals: 1. To establish a prostate cancer data and tissue repository; and 2. To utilize the repository to test whether prostate cancer is related to interindividual variability in the response to genotoxic stress.

Consultants, if any	**Department or Institution**
Asim Amin, M.D.	Medicine and Oncology, Georgetown University
Anatoly Dritschilo, M.D.	Radiation Medicine, Georgetown University
John Lynch, M.D.	Urology, Georgetown University
Peter Shields, M.D.	Oncology, Georgetown University
Bhaskar Kalakouri, M.D.	Pathology, Georgetown University
Mohan Verghese, M.D.	Radiation Oncology, Washington Hospital Center
Michael Porrazzo, M.D.	Urologic Oncology, Washington Hospital Center
Pamela Randolph, M.D.	Medical Oncology, Washington Hospital Center

Estimated duration of total project	3 years
Estimated total number of subjects (including control subjects)	600
Age range of subjects	>18
Sex of subjects	Male

Where will study be conducted?	GUMC
Source of subjects	Georgetown University Hospital and Washington Hospital Center

Grant Support for Project (if any)	**Commercial Support (if any) for Project**
Funded in part by the Department of Defense. Additional funding will be provided by the Lombardi Cancer Center and the protocol will be conducted by the GCRC laboratory. Once pilot data is obtained, additional grant funding will be sought.	

Investigational New Drug (IND)	**Investigational Device Exemptions (IDE)**
❑ None ❑ IND: FDA No. _____ ❑ Drug Name: _____ ❑ Drug Sponsor: _____	❑ None ❑ IDE: FDA No. _____ ❑ Device Name: _____ ❑ Device Sponsor: _____ ❑ Significant (SR) ❑ Non-Significant Risk (NSR)

MedStar Research Institute-
Georgetown University Oncology
Institutional Review Board

IRB Number: _____

Section Two: Additional MedStar Research Institute-Georgetown University Regulatory Information

1. Does this project involve the use of biohazardous materials, recombinant DNA and/or gene therapy?
   - ❑ Yes. If so, Institutional Biosafety Committee (IBC) approval must be obtained. Contact 202-687-4712 for assistance.
   - √ No.

2. Has the Institutional Biosafety Committee approved the protocol?

√ NA

❑ **Approved**	**Date Approved:**
❑ **Application Pending**	**Date Submitted:**

3. Does this project include the use of radioisotopes and/or radiation-producing devices regardless of whether the use is incidental to the project?
   - ❑ Yes. If so, all protocols must be submitted to the GUH RSC along with a completed RSC-4 or RSC-5 form. The forms require information on the use of radioisotopes and radiation-producing devices and must include dose calculations. Call 202-687-4712 to obtain forms or if additional information is required.
   - ❑ No.

4. Has the Radiation Safety Committee approved the protocol?

√ NA

❑ **Approved**	**Date Approved:**
❑ **Application Pending**	**Date Submitted:**

5. Does this project involve the use of fetal tissue?
   - ❑ Yes
   - √ No

6. Do any investigators or co-investigators have a conflict of interest as defined in the Georgetown University Faculty handbook or MedStar Health Institute policy?
   - ❑ Yes. If yes, please explain.
   - √ No

7. A copy of each investigator's current Conflicts of Interest Disclosure Form must be attached to this application.

If this project involves a FDA regulated drug or device, you must file a FDA form 3455.

Section Three: Information for Protocol Review
Please answer each specific question and use additional sheets as needed. A response of "See attached protocol or grant application" is not sufficient.

6. Provide a brief historical background of the project with reference to the investigator's personal experience and to pertinent medical literature. Use additional sheets as needed.

Despite the fact that prostate cancer is the most common tumor among US males, relatively little is known about the causative mechanisms. The known risk factors include age, ethnicity or race, high-fat diet and family history of prostate cancer, but these factors are not sufficient for identification of men with increased susceptibility. Establishing new biomarkers of cancer risk would greatly benefit the field of prostate cancer prevention and surveillance.

Mutagen sensitivity and comet assay are established biomarkers of risk (1). The mutagen sensitivity assay measures response to a genotoxic insult (e.g. bleomycin exposure) in short-term cultured human lymphocytes in terms of the number of chromatid breaks; comet assay measures DNA unwinding under alkaline conditions. Subjects with a high number of chromatid breaks in mutagen sensitivity assay or high DNA unwinding in comet assay have higher cancer risk. For example, comparison of cancer risk in the highest/lowest quartile of mutagen sensitivity in a study of 150 head and neck cancer cases and 150 controls matched on age and race showed an odds ratio of 4.5 with p=0.04 (2). Surprisingly, these phenotypic assays were not yet examined in prostate cancer. Even though the exact mechanism underlying the phenotypes is unknown, variability in DNA-repair capacity is consistent with the available experimental results (3). Moreover, it was shown in twin studies that mutagen sensitivity is heritable in non-cancer subjects. The correlation coefficient was 0.79 (95% confidence interval = 0.65-0.88) in monozygotic twins while for dizygotic twins the coefficient was 0.42 (95% confidence interval = 0.00-0.71) (4). Mutagen sensitivity and comet assay phenotypes therefore reflect multiple genetic traits related to DNA repair capacity, which predispose an individual to cancer risk.

Apoptosis is a molecular pathway eliminating, besides other functions, cells unable to cope efficiently with genotoxic stress. Deficient apoptosis is a likely candidate for a cancer-prone phenotype. Apoptosis was implicated in regulation of response to radiation therapy in prostate cancer (5), malignancy of prostatic tumor (6), and recurrence of prostate carcinoma following surgery (7). For example, in 54 prostate cancer patients treated with radiotherapy the response was negative in 84% cases with positive bcl-2 immunohistochemistry and bcl-2 was an independent prognostic variable for treatment with odds ratio of 7.3 (5). Apoptotic index was associated with disease recurrence in a study of 47 men following radical prostatectomy (7). But apoptosis was not yet examined as a phenotypic predictor of prostate cancer risk. Since the apoptotic phenotype is a composite measure of a number of converging mechanistic pathways, it is advantageous to the measurement of each individual genotype in the pathway.

Lipid peroxidation was suggested as a mechanism underlying the association of dietary fat and prostate cancer risk. Lipid peroxidation leads to oxidative genotoxic stress, that can overwhelm DNA repair and/or apoptotic mechanisms and potentially lead to cancer. We propose to quantify malondialdehyde deoxyguanosine adducts (dGMDA) in peripheral blood lymphocytes and prostate tumors. HPLC methods will be used for all assays.

DNA repair consists of two major categories, excision repair (base excision repair and nucleotide excision repair) and recombination repair (homologous and non-homologous) (8). Numerous polymorphisms in the DNA repair genes have been identified (9) and are likely to contribute to cancer risk through decreased efficiency of response to genotoxic stress. But two functional polymorphisms in DNA repair genes, *OGG1* and *XRCC1*, are particularly relevant to this study. Both genes are involved in the repair of 8-hydroxy-guanine (8-OHdG) and other oxidative lesions (10); and our study examines mainly how variability in the response to oxidative DNA damage modifies risk for prostate cancer

(bleomycin is a radiomimetic which induces oxidative DNA damage and mutagen sensitivity is mainly a model of this pathway). OGG1 is a DNA glycosylase/AP lyase involved in base excision repair of 8-OHdG and XRCC1 is a DNA ligase III terminating the base excision repair cascade (10). The OGG1 Ser(321)Cys polymorphism codes for a protein with a lower 8-OHdG repair capacity and leads to several splicing variants of unknown functional significance (11). This variant occurs at a frequency of 0.4 in Japanese and was associated with an increased risk of lung cancer in a study of 241 cases and 197 controls with an OR=3.01 (95% CI 1.33-6.83) (12). This variant was found in a Caucasian population at a frequency of 0.22 and was not associated with lung cancer in this study (13). Examination of this polymorphism in prostate cancer is therefore highly relevant. The XRCC1 Arg(399)Gln polymorphism was associated with increased sensitivity of human lymphocytes to DNA damage (14), increased risk of squamous cell carcinoma of the head and neck (15), increased risk of early onset colorectal carcinoma (16), and increased risk of adenocarcinoma of the lung (17). The polymorphism occurs in 37% of Caucasians and 17% of African-Americans (19). An examination of the XRCC1 'at risk' polymorphism as a risk factor for prostate cancer was not reported.

The study of mutations in human tumors and experimental models is elucidating important carcinogenic mechanisms (20). The study of mutations in the p53 tumor suppressor gene is uniquely suited for the study of cancer etiology, because p53 is involved in many cellular processes (including maintenance of genomic stability, programmed cell death, and DNA repair) and in tumors often accumulates point mutations amenable to further analysis (21). Specific mutations in p53 can reflect carcinogenic insults that precede cancer. It was shown that reactive oxygen species are a major source of G:C -> A:T transitions at non-CpG sites. For example, in radiation-induced lung cancer, G:C -> A:T transitions at non-CpG sites dominate the p53 mutational spectra, which differs markedly from mutational spectra associated with tobacco (22,23). Oxidatice damage is expected to be a major source of DNA damage in prostate cancer. Mutagen sensitivity and comet assay are a model of oxidative DNA damage (bleomycin is a radiomimetic which induces oxidative DNA damage), and *OGG1* and *XRCC1* participate in the repair of oxidatively damaged DNA. We therefore predict that G:C -> A:T transitions at non-CpG sites will correlate with mutagen sensitivity/comet assay phenotypes and at risk variants of *OGG1* and *XRCC1*. This study would provide for the first time an evidence for such an association. The p53 gene is also an attractive target because it is mutated in up to 35% of early prostate cancers (24).

Significance: We are proposing a molecular epidemiology study to test variation in the response to genotoxic stress and in DNA repair as a biomarker of prostate cancer risk. This study measures mutagen sensitivity, comet assay, apoptosis, and polymorphism in *OGG1* and *XRCC1* as biomarkers of prostate cancer risk; the study also correlates mutations in p53 tumor supressor gene with mutagen sensitivity. The proposal is innovative because neither of the proposed biomarkers was to our knowledge examined in connection with prostate cancer risk. If mutagen sensitivity, apoptosis, or DNA repair-variants correlate with prostate cancer risk, they could serve as readily obtainable biomarkers to identify men with increased risk of prostate cancer. The phenotypic biomarkers could be used to better identify the currently poorly understood genotoxic insults leading to cancer risk (improved risk models in case-control studies). Elucidating mechanisms of the early stages of prostate carcinogenesis would have an immediate impact for prevention and surveillance. Better prevention strategies (including chemoprevention) could be designed and tested based on the identified targets. And new hypotheses focusing on the genetic and environmental factors associated with prostate cancer risk could be formulated and evaluated.

Dr. Radoslav Goldman, Principal Investigator: Dr. Goldman is Assistant Professor of Oncology and a member of the Cancer Genetics and Epidemiology Program at LCC. He is an analytical toxicologist with specialization in biomarker studies of cancer risk. Dr. Goldman will be responsible for the design and execution of the proposed study, data analysis, and result interpretation. He will work in close collaboration with Dr. Loffredo and Dr. Shields on the establishment of the prostate biomarker resource.

Dr. Christopher Loffredo, Co-Investigator: Dr. Loffredo is Assistant Professor of Oncology and a member of the Cancer Genetics and Epidemiology Program at LCC. He is responsible for the

epidemiological field activities of the Biomarker Core Resource. Dr. Loffredo will assist with the coordination of the collection and transfer of specimen, repository, and statistical analyses.
Dr. Asim Amin, Consultant: Dr. Amin is Assistant Professor of Medicine and Oncology. He will refer patients from this department to the study coordinator.
Dr. Anatoly Dritschilo, Consultant: Dr. Dritschilo is Professor and Chairman of the Department of Radiation Oncology and will refer patients from this department to the study coordinator.
Dr. John Lynch, Consultant: Dr. Lynch is Professor of Surgery and Chairman of the Department of Urology. He will refer patients from this department to the study coordinator.
Dr. Peter Shields, Consultant: Dr. Shields is Professor of Oncology and Medicine, Director of Cancer Genetics and Epidemiology Division, and Associate Director for Population Sciences. Dr. Shields will assist in the design and oversight of the study.
Dr. Bhaskar Kalakouri , Consultant: Dr. Singh is Assistant Professor of Pathology and will oversee the collection and processing of prostate tissue for this study.
Dr. David Perry, Consultant: Dr. Perry is Medical Director of Clinical Research, Washington Hospital Center, and will refer patients to the study and help us coordinate recruitment effort at this hospital.
Dr. Mohan Verghese, Consultant: Dr. Verghese is from the Department of Radiation Oncology, Washington Hospital Center, and will refer patients from this department to the study coordinator.
Dr. Michael Porrazzo, Consultant: Dr. Porrazzo is from the Department of Urologic Oncology, Washington Hospital Center, and will refer patients from this department to the study coordinator.
Dr. Pamela Randolph, Consultant: Dr. Randolph is from the Department of Medical Oncology, Washington Hospital Center, and will refer patients from this department to the study coordinator.

7. The plan of study. State the hypothesis or research question you intend to answer. Describe the research design and procedures (including standard procedures) to be used in the research. Specifically identify any experimental procedures. Provide statistical justification for the number of subjects to be studied and the degree of change expected. Describe any special equipment or unusual procedures to be used for this research project. Use additional sheets as needed.

Research Question: This study has two goals: 1. To establish a prostate cancer data and tissue repository; and 2. To utilize the repository to test our hypothesis that prostate cancer is related to interindividual variability in the response to genotoxic stress. We propose to examine 1. Mutagen sensitivity, comet assay, and apoptotic response to bleomycin in peripheral blood lymphocytes; 2.; dGMDA adduct in lymphocytes and prostate tissue and 3. Genetic variants of the DNA repair genes *OGG1* and *XRCC1* as biomarkers of prostate cancer risk. In selected cases, we will examine the association of p53 mutational spectrum with mutagen sensitivity and genetic polymorphisms in *XRCC1* and *OGG1*.

Specific Aims: This study can address several areas of prostate cancer by developing the infrastructure to allow us to identify new biomarkers of prostate cancer risk, and improve our ability to optimize prevention and treatment strategies for prostate cancer. We plan to develop an ongoing recruitment of prostate cancer cases so that we can study prostate tumor tissue, blood and other specimen in order to understand the genotypic and phenotypic expression (e.g., mutagen sensitivity) of possible prostate cancer risk markers and to establish genotype-phenotype relationships. By linking an epidemiological profile to the tissue tumor markers, we will be able to elucidate gene-environment interactions by performing a case-control analysis and searching for etiological clues in the tumor tissue (e.g. p53 mutational spectra). The genetic risk markers under study will be limited to low penetrance genes that modulate the risk of prostate cancer and carry a risk in the context of prostate cancer of about 2-fold.

The specific aims and hypotheses of this project are to:

1. Recruit prostate cancer cases and controls to provide an epidemiological profile, blood, urine, nail clipping, and tumor tissue (when available). This will establish a data and tissue repository.

2. Utilize the repository to study low penetrance genes, investigate gene-environment interactions and establish genotype-phenotype relationships involving DNA damage, DNA repair and response to DNA damage, in order to identify or validate the use of intermediate biomarkers of cancer risk.

- H_{2a} High mutagen sensitivity/comet assay increase the risk of prostate cancer.
- H_{2b} Low apoptotic response increases the prostate cancer risk.
- H_{2c} High dGMDA adducts increase prostate cancer risk.
- H_{2d} At risk variants of XRCC1 and OGG1 increase prostate cancer risk.

3. To identify the relationship of biomarkers measured in surrogate tissues such as blood, buccal swabs and urine to pathological markers in prostate tumor. Investigate gene-environment interactions and establish genotype-phenotype relationships involving DNA damage, and response to DNA damage, in order to identify or validate the use of intermediate biomarkers of cancer risk.

- H_{3a} Comet assay/dGMDA in lymphocytes correlate with these markers in prostate tissue.
- H_{3b} Genetic polymorphism of DNA repair-genes is associated with p53 mutations.
- H_{3c} Mutagen sensitivity is associated with p53 mutations.

Methods: Cases will be enrolled from the Departments of Medicine and Oncology, Radiation Medicine, and Urology at the Georgetown University Medical Center and Washington Hospital Center.

Approximately 200 newly diagnosed patients with prostate cancer are treated currently each year at each clinic, which is more then enough for our goal to enroll 300 patients in three years. All participants will be requested to complete an informed consent and undergo a forty five minute interview, phlebotomy, buccal cell collection and provide a nail clipping and urine sample. Also unneeded pathological tissue from patients (tumor and adjacent normal tissue) will be collected if available. A repository will be established for future studies as new hypotheses are generated.

The weekly schedule for the clinic is available to the phlebotomist/interviewer so that he/she can determine the times when eligible patients are in the clinic. Most such patients are seen at the clinic once or twice prior to their surgery so there is ample opportunity to enroll them prior to any treatment. Dr. Amin and the other consultants will inform the patients about the study and those who are potentially interested will meet the phlebotomist/interviewer. If a subject refuses to participate, then he is given the "Questions for Decliners" form and no further contact is made. The study coordinator explains the study, determines eligibility, obtains informed consent, and if appropriate administers a questionnaire, withdraws 45 cc of blood, collects buccal cells, obtains nail clipping and a urine sample in collaboration with the GCRC laboratory. As the patients await their examination in the clinic, they are accompanied by the phlebotomist/interviewer who helps them with orientation in the building etc. This gives also opportunity to answer the preliminary questions and to set a time for the full questionnaire/sample collection. This method worked well in our previous studies.

Controls are obtained from visitors accompanying other patients to the hospital. The interviewer identifies potential candidates, investigates their willingness to participate, and screens for eligibility using a script (Script 2-Control Recruitment in Clinic Area) and the eligibility screening form. The subjects usually accompany a person to the hospital on a regular basis. These controls are easily contacted and typically motivated to participate. The interviewer creates a list of willing, eligible controls and recruits from the list to the study when a match is identified. The controls are unbiased with respect to geography and socioeconomic status because they come to the hospital from the same geographic referral area as the cancer cases. In addition, controls can be obtained from neighbors and friends of the patients. Each patient can nominate up to 5 people living in the same geographical area and of the same race and age (within 5 years). The patients are asked to verify with the nominees about their agreement to be contacted by the phlebotomist/interviewer. A random drawing from the list of candidates will be performed and a candidate will be contacted. Up to three phone calls will be placed. If the subject does not return the phone calls, then it is assumed that he is uninterested in participating. In the event that a subject cannot be reached by phone, he will be contacted by mail. In case of refusal, next candidate is then randomly selected from the list of nominees. An attempt is made to collect information on age, race, smoking and drinking history of those who refuse to participate to determine whether they differ from participants demographically or by exposures. If a matching control cannot be found among the nominees, a match is identified from the pool of all eligible controls in the study. The phlebotomist/interviewer works from a list of the cases that have been enrolled up to that time, so that he/she can identify appropriate matches. Eligibility of interested controls to participate is determined over the phone by the phlebotomist/interviewer according to the telephone script. The interested candidates are invited to the Georgetown Hospital to finish a full questionnaire, donate a 45cc blood sample, a sample of buccal cells, and a sample of urine. PSA will be tested by the GCRC for all controls to exclude misclassification. Controls with PSA > 2.5ng/ml will be referred to a clinician for a follow-up testing. In this way, we obtain controls individually matched on race and age (within 5 years). Informed consent is obtained at the time of interview.

Additionally, all men undergoing a prostate biopsy at GUMC will be given a "consent to participate in research" form. Of those that consent to participate in research, the patients whose biopsy is positive will be recruited into the Case group, while the patients whose biopsies are negative will be recruited into the Control group. This control group of men with confirmed negative biopsies will constitute a group of men with Benign Prostatic Disease, and will be a separate control group from those who have no diagnosis of

prostatic disease and have never received a biopsy.
It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as part of their responsibility to protect human subjects in research. Also, if any changes to the protocol or consent form are made, they are to be reviewed and approved by the Human Subjects Research Review Board prior to implementation.

Reporting of Serious and Unexpected Adverse Events:
Unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study, and all study-related subject deaths will be promptly reported by phone (301-619-2165), by email (hsrrb@det.amedd.army.mil), or by facsimile (301-619-7803) to the Army Surgeon General's Human Subjects Research Review Board (HSRRB). A complete written report will follow the initial telephone call. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Materiel Command, ATTN:MCMR-ZB-QH, 504 Scott Street, Fort Detrick, Maryland 21702-5012."
Procedures: Subjects are identified by review of appointment logs and discussion with doctors. Subjects are contacted during their visit to the clinic (patients), in the clinic waiting areas (controls), or by phone (controls nominated by the patient). The phlebotomist/interviewer assists the patient during his visit to the hospital, determines eligibility, explains the study and obtains informed consent, administers the questionnaire and collects 45cc of blood, buccal cells, nail clipping and a sample of urine together with the GCRC laboratory. The interviewers are trained through the GCRC in how to administer and properly complete the questionnaire. Dietary exposures (high fat etc.) will be assessed using the well-validated questionnaire developed by Dr. Gladys Block, NCI, NIH. Phlebotomy is performed by trained phlebotomists. There will be a single blood draw, using these tubes in the following order: two 7 ml green top tubes, two 7 ml plain red top tubes, one 10 ml yellow top tubes, and one 7 ml purple top tube. Only a portion of the collected samples is used for the currently planned specific aims. The remainder of the samples is aliquotted and frozen at -70°C for future studies. There will be blood for multiple aliquots of buffy coat, mononuclear cells, PMNs, serum, plasma, red blood cells and clots. This strategy will allow us to test new hypotheses and assess new genetic predispositions as they are deemed worthy of study. If the subject is going to surgery, residual normal and tumor prostate tissue is placed into aliquots and snap frozen. Two samples of the normal and tumor tissues is saved, one without preservative and one with RNA later for preserving RNA. Tumor tissue is also fixed in formalin and ethanol. When available from surgery, normal cells are collected to establish primary cell cultures. If a subject is not going to surgery, but the subject had surgery at the University, then tumor blocks are requested from the LCC histopathology core. Medical records are reviewed to obtain pathological and clinical data. If a subject chooses to withdraw from the study, the link between his identity and the research study will be destroyed. Also, his biological samples will be discarded. However, the results of any finished analysis and or published result will be kept to preserve the integrity of the study.

Laboratory Methods: All the methods follow an established protocol. The mutagen sensitivity, comet assay, and apoptosis are carried out on short-term (3 day) cultured human lymphocytes exposed to bleomycin (2). The samples of isolated DNA for dGMDA quantification are sent to outside collaborators for analysis. These samples will contain only the identifier code so that there is no possibility to disclose personal information. The dGMDA is quantified by gas chromatography/negative chemical ionization mass spectrometry (25). Genetic polymorphisms are analyzed by PCR-RFLP as described (12)(19). Mutational spectra of p53 are analyzed in isolated DNA by the affymetrix chip in the laboratory of Dr. Shields (26).
Statistical Power: The present proposal intends to study 300 prostate cancer cases and 300 matched controls. The matched-pairs design increases statistical power to detect a meaningful relative risk since matched-pairs data would gain relative efficiency in estimation. Suppose the hypothesis of interest is that

having a certain biomarker (e.g. mutagen sensitivity) increases the probability of developing prostate cancer, with the null hypothesis being that such probability is the same with or without the biomarker. Let p be the population frequency of having such biomarker, and let r be the relative risk defined as the ratio of the frequency of prostate cancer with the biomarker to the frequency of prostate cancer without the biomarker. Then for r=2.5, the statistical power with 5% level of significance (two-sided) will be 84%, 89%, and 93%, respectively, if p=20%, 25%, and 30%, accordingly. In our case, for example, the frequency of mutagen sensitive subjects in the population was estimated as 20% (6) and the *XRCC1* 'at risk' allele as 25% in the general population (19). The statistical power would be relatively lower when the comparison is controlled by other factors such as race. It should be noted that tests of effect modification or associations are exploratory, and the study was not designed to have optimal power for those analyses. All the analyses will be performed using the Statistical Analysis System (SAS) and S-plus statistical software packages.

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8. Indicate what you consider to be the risks to subjects and indicate the precautions to be taken to minimize or eliminate these risks. Justify the need for a placebo control group if one is included in this study. Where appropriate, describe the data monitoring procedures that will be employed to ensure the safety of subjects. Use additional sheets as needed.

There are minimal risks for this study. The only invasive procedure is phlebotomy. This may cause a bruise on the arm from the needle stick and possibly an infection. These risks are minimized through proper techniques for phlebotomy and the trained staff is experienced in reducing discomfort to patients. The actual surgery or clinical practices related to the prostate cancer will not be altered for this study.

Section Four: Selection of Subjects and the Informed Consent Process

9. Indicate whether this project involves any of the following subject populations?
   - ❑ Children (Children are defined by local law as anyone under age 18.)
   - ❑ Prisoners
   - ❑ Pregnant women
   - ❑ Cognitively impaired or mentally disabled subjects
   - ❑ Economically or educationally disadvantaged subjects

If you indicated any of the above, in the space below, please describe what additional safeguards will be in place to protect these populations from coercion or undue influence to participate. (Use additional sheets as needed.)

10. Describe how subjects will be recruited and how informed consent will be sought from subjects or from the subjects' legally authorized representative. If children are subjects, discuss whether their assent will be sought and how the permission of their parents will be obtained. Use additional sheets as needed.

This is a study of prostate cancer risk factors that enrolls newly diagnosed, incident prostate cancer cases from the Departments of Medicine and Oncology, Radiation Medicine, and Urology at the Georgetown University Medical Center. The eligible patients donate their time for a questionnaire; blood and urine samples; buccal swabs; nail clipping; and unneeded normal and tumor prostate tissue. Subjects are eligible and will be enrolled even if they are not having a surgery or biopsy and if no tissues are available. Subjects older than 18 years of age at all stages of presentation are included. No subject is excluded based on minority status. Subjects with psychiatric disorder or any other reason that precludes understanding the informed consent are excluded for ethical reasons. The phlebotomist/interviewer conducts a brief initial 15 minute interview in order to explain the study, determine eligibility, and explain the informed consent. If a subject refuses to participate, then no further contact is made. If appropriate, the phlebotomist/interviewer administers a structured forty five minute interview that establishes demographic characteristics, family history of cancer, dietary habits, tobacco and alcohol use, occupational exposures, and history of vasectomy. This interview can be done at any time up to two months after initiation. The phlebotomist/interviewer will also withdraw 45 cc of blood, collect buccal cells, obtain nail clipping and a urine sample in collaboration with the GCRC laboratory at Georgetown University.

Controls are obtained from visitors accompanying other patients to the hospital. The interviewer identifies potential candidates, investigates their willingness to participate, and screens for eligibility using a one-page form. The interviewer creates a list of willing, eligible controls and recruits from the list to the study when a match is identified. In addition, controls can be obtained from neighbors and friends of the patients. Each patient can nominate up to 5 people living in the same geographical area and of the same race and age (within 5 years). The patients are asked to verify with the nominees about their agreement to be contacted by the phlebotomist/interviewer. The controls are randomly selected from the list of candidates and contacted by the interviewer. Up to three phone calls are placed. If the subject does not return the phone calls, then it is assumed that he/she is uninterested in participating. In case of refusal, next candidate is randomly selected from the list of nominees. An attempt is made to collect information on age, race, smoking and drinking history of those who refuse to participate to determine whether they differ from participants demographically or by exposures. A subsequent meeting with the matching

control is scheduled. During this meeting, the interviewer explains the study in detail and obtains informed consent. A full length questionnaire as well as blood , buccal, urine, and nail-clipping samples are obtained. The samples or questionnaire can be obtained also at a later visit up to two month following the initial contact if this is more convenient for the participant.

11. Will subjects receive any compensation for participation in cash or in kind?
    - √ Yes. If so, please describe amount or kind of compensation in the space below.
    - ☐ No.

Patients will not be compensated. Controls will receive free PSA test if needed and $25 for parking if study funds permit.

Section Five: Privacy and Confidentiality of Data and Records

12. Will identifiable, private, or sensitive information be obtained about target the subjects or other living individuals? Whether or not such information is obtained, describe the provisions to protect the privacy of subjects and to maintain the confidentiality of data. Use additional sheets as needed.

There are minimal risks of disclosure of sensitive information in this study, but there is always the risk that genetic or other risk factor data might be obtained by the subject or a third party. However, it is important to realize that the genes studied herein are low penetrant. We study only common genetic polymorphisms in DNA repair genes and somatic mutations in p53; we do not study familial germ line mutations. This risk of disclosure will be minimized by the confidentiality and protection of privacy procedures described below.

Protection of privacy of participants in genetic studies is of the utmost importance. Study subject's confidentiality is maintained at all times. Subjects are assigned unique study numbers. These unique study numbers are linked to the subject's identifier information in a database and on the hard copy of the Identifier Sheet. This information is secured by Dr. Goldman in his office separate from the laboratory. The database requires at least two levels of security (i.e. passwords), which allows only authorized individuals to access the information. The Identifier Sheets are physically separated from the questionnaire and stored in a locked cabinet. The questionnaire retains only the unique study number. Biological samples are labeled with the unique study number and no other identifier information. No identifier information that can be linked to study results or other data will leave Dr. Goldman's premises.

Identifier information for non-participants (refusers and ineligibles) is recorded in order to avoid recontact. This information is stored in a database with at least two levels of security (i.e. passwords), which allows only authorized individuals to access the information. A log will automatically note who accesses the information and what was accessed. Unique study number for non-participants is also assigned; this is used for tracking reasons. Two databeses are maintained. The first includes the Contact Database and includes identifier information. It will record if subjects refused, were ineligible, or are participants. If participants, it will record when the interview occurred or will occur, the outcome, and track sample handling. For refusers and ineligibles, it will record that their data was entered into the Refusal and Ineligible database. The Refusal and Ineligible database will record data and why the subject was ineligible. This database does not contain identifier information.

MedStar Research Institute-
Georgetown University Oncology
Institutional Review Board

IRB Number: _____

I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any modification in the protocol or informed consent document and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study.

I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

Printed/Typed Name of Investigator	Telephone number
Signature of Investigator	Date
Department Chair: ☐ Approved ☐ Disapproved Printed/Typed Name	Telephone Number
Signature of Department Chair	Date

If more than one department or administrative unit is participating in the research and/or if the facilities or support of another unit, e.g., nursing, pharmacy, or radiation therapy, are needed, then the chair or administrative official of each unit must also sign this application.

Authorized Signature and Title	Date
Authorized Signature and Title	Date
Authorized Signature and Title	Date
Authorized Signature and Title	Date
Authorized Signature and Title	Date

Section Six: Attachments

Please attach the following items in order for the IRB to review your research.

1. 24 copies of this IRB Application form
2. The informed consent document (24 copies)
3. Any recruitment notices or advertisements (24 copies)
4. Any research survey instruments, psychological tests, interview forms, or scripts to be used (24 copies).
5. Certificate of Completion of Education in the Protection of Human Research Subjects
6. Investigator's qualifications (CV, biosketch, or Form 1572, if available)
7. Investigator's Brochure from the sponsor, if applicable (5 Copies)
8. Research protocol and sample consent document from the sponsor or Cooperative Group, if applicable (5 copies)
9. Grant application, if applicable (2 copies)

Investigator's Brochure (where applicable)

The Investigator's Brochure must contain the following information. If it does not contain the information, then please attach a separate sheet of paper to address the item.

(a) Name of drug under study.
(b) Source of the drug.
(c) Experience with the drug in humans, including doses tested, toxicity observed, minimal toxic dose, pharmacokinetic data (absorption, elimination, metabolism, etc.).
(d) Description of toxicity in humans.
(e) Procedures for minimizing adverse reactions and dealing with those that might occur.

Mutagen Sensitivity Eligibility Criteria

Name: _____ MR# _____

1. Have you had a previous diagnosis of any cancer? ( ) Yes ( ) No
   If yes, what kind of cancer?_____

2. Have you received chemotherapy for any reason within the past 6 months?
   ( ) Yes ( ) No
   If yes, what dates? _____

3. Have you received radiation for any reason within the past 6 months?
   ( ) Yes ( ) No
   If yes, what dates? _____

4. Have you had any surgeries within the past month that required anesthesia?
   ( ) Yes ( ) No

5. Are you being treated for infection or have you taken antibiotics within the past 12 days?
   ( ) Yes ( ) No
   When will you finish your antibiotics? _____

6. Have you received a blood transfusion within the past 6 months?
   ( ) Yes ( ) No

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7. Are you taking any steroids or immunosuppressive medications?
   ( ) Yes ( ) No
   When will you finish your medications? _____

8. Do you have a known diagnosis of HIV, hepatitis B or C?
   ( ) Yes ( ) No

9. Are you an IV drug user?
   ( ) Yes ( ) No

****

MEDICAL RECORDS RELEASE AND GENERAL AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION FOR RESEARCH

I agree to allow Dr. Goldman and his staff (together called "Researchers"), as well as the study sponsor, Lombardi Cancer Center of Georgetown University, others working with the sponsor to do the research (together called "Sponsor"), and the other people or companies listed below, to use and give my personal health information that identifies me for the reason described in the Informed Consent Form used for this study and as needed to conduct the research. I also agree to allow Georgetown University Hospital, my doctors and my other health care providers, and others who generate or use my health information, to give my health information in my medical or other records to the Researchers and Sponsor for the purposes described below and in the Informed Consent Form used in this study. [IRB Project # 03013 and Project Full Title: The Molecular Epidemiology of Prostate Cancer]

1. **The health information that may be used for this study includes:**
   - ☒ All my personal information made or collected during the research described in the Informed Consent Form for this study; and
   - ☒ All my personal information in my medical records requested by the Researchers to be able to do the research described in the Informed Consent Form for this study.

   OR

   - ☐ The following information: _____

2. **The person(s), class(es) of persons, and/or organizations (companies) who may use, give and receive the above information include*:**
   - ☒ Every research site for this study, including the hospital, and including each site's research staff, medical staff and administrative staff;
   - ☒ Health care providers who provide services to me in connection with this study;
   - ☒ Laboratories and other individuals and organizations that look at my health information in connection with this study, in agreement with the study's protocol;
   - ☐ The Sponsor and the people and companies that they use to watch over how the study is managed, run, or do the research as described above;
   - ☐ The United States Food and Drug Administration (FDA) and other Federal or State Agencies that watch over the safety of the study and how the study is managed or run;
   - ☒ The members and staff of the Institutional Review Board(s) or Ethics Committee(s) that approves this study;
   - ☒ The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge for doing all the work for the study and other research activities;
   - ☐ The Patient Advocate or Research Ombudsman (people who watch out for my best interest): _____
   - ☐ Data Safety Monitoring Boards (a group of people who examine the medical information during the study) and other government agencies or review boards who watch over the safety, success and how the research is done.
   - ☐ Others: _____

   **If, during the course of the research, one or more of the companies or institutions above merges (becomes one company) or is bought by another company, this Authorization will remain valid.*

3. **Once my health information has been given to one of the person(s), class(es) of persons, and/or organizations (companies) listed above**, there is the possibility that federal privacy laws (laws that protect the privacy to my personal health information) may no longer protect it from being given to

another person, class of persons, and/or company. However, the Researchers and Sponsor [may agree/have agreed] to further protect my health information by using and disclosing it only for the research purposes described in the Informed Consent Form and as allowed by me in this Authorization (agreement). Also, the Researchers and Sponsor [may agree/have agreed] that no publication or presentation of the research will reveal my identity without my separate specific written permission and authorization (agreement). These limitations, if agreed to by the Researcher and Sponsor, continue even if I revoke (take back) this Authorization (agreement).

4. **Once information that could be used to identify me has been removed and my information is no longer identifiable (connected to my identity) under federal regulations,** the information that remains is no longer protected by this Authorization (agreement) and may be used and given by the Researchers and Sponsor as permitted by law to others, including for other research reasons.

5. **I understand that:**
   - I have the right to refuse to sign this Authorization (agreement). While my health care outside the study, the payment for my health care, and my health care benefits will not be affected if I do not sign this form, I will not be able to participate in the research described in this Authorization (agreement) and will not receive treatment as a study participant if I do not sign this form.
   - I may change my mind and revoke (take back) this Authorization (agreement) at any time. To take back this Authorization (agreement), I must write to: Alexandra Schopf, Lombardi Cancer Center, Lower Level Room S-157, Georgetown University, Box 571472, Washington, DC 20057-1472 . However, if I take back this Authorization (agreement), I may no longer be allowed to participate in the research. Also, even if I take back this Authorization (agreement), the information already obtained may remain a part of the research as necessary to preserve the integrity of the research study.

6. **This Authorization (agreement) does not have an expiration (ending) date.**

7. **I will be given a copy of this Authorization (agreement) after I have signed it.**

8. **I acknowledge that I have received or declined the pamphlet with the MedStar Health Notice of Privacy Practices and that this form is available for me to take with me.**

Signature of participant or participant's legal representative	Date
Printed name of participant or participant's representative	Representative's authority to sign for participant

For Internal Use Only

Signature/acknowledgement of receipt of Notice of Privacy Practices not obtained because:

- ☐ Emergency
- ☐ Patient/Patient Representative declined to sign
- ☐ Patient/Patient Representative unable to sign

MRI Representative

TELEPHONE CONTACT-Prostate

- Hi my name is Alexandra Schopf and I am calling from the Lombardi Cancer Center at Georgetown University. You were referred to me by Dr.....who is conducting a research study with us here at LCC. Dr. .....suggested I contact you and ask you to participate. My colleague, Tara Lamond, may have already spoken with you regarding her study. Please understand that these are two different studies, but are complementary to each other.
- I would like to tell you a little more about this research project designed to improve our understanding of prostate cancer.
- The Study is entitled "Prostate Cancer Biomarker Resource" and is funded through the Department of Defense.
- Our objective is to provide our medical researchers with an epidemiological profile in the form of a questionnaire as well as biological samples. Thus, should you choose to participate you will first be asked to sign an informed consent form, take part in a ten minute interview and to provide a small sample of blood, urine, mouthwash and a toenail sample.
- I would just like you to know that all information is kept strictly confidential. There is no information listed on the questionnaire or biologic specimen to reveal your identity. Additionally, joining the study is completely voluntary and will have no positive or negative effect on your relationship with your doctor, treatment plans etc.
- Your participation in this study will help us test new methods for early diagnosis and treatment of prostate cancer. Such information is invaluable for both present and future patients. Does this sound like something you would be interested in participating in?
- IF NO – could I ask you why you are not interested? Also, could I ask you just a few questions? What is your occupation? Do you smoke tobacco or drink alcohol on a regular basis? (Also, find out race, DOB, and enter all information in database)

  Then-Thank you very much for your time. Best wishes for a fast recovery.

  IF YES – I just want to confirm
  1. Have you ever had cancer before?
  2. Have you had any chemotherapy or radiation in the past 6 months?
  3. Have you had any MAJOR surgeries (biopsy is not major) in the past 3 months?
- (If no to all 3 questions) OK, we can schedule an appointment to meet either before or after your next visit to GU. When is that? (or, if you would like to make a separate trip, we can pay for parking). It will take about one hour for me to explain the study, have you sign the consent forms, collect your biological samples and conduct the ten minute interview. (Agree on time and place to meet). Also, sir, please don't clip your toenails for about a week before our appointment. Thank you. See you soon.

Control recruitment protocol-approaching people in clinic waiting areas

(Interviewer carries 'matching' chart with her/him around clinic, approaches men who appear to fit the needed demographics)

- Excuse me sir (male between 18 and 90 yrs old-ask if unsure), are you a patient here?
- If cancer patient: Thank you. If patient seems curious, explain: I am working on a research study here and looking for people who are here accompanying patients.
- OTHERWISE: Hi I'm Alexandra Schopf. I'm working on a research project designed to improve our understanding of prostate cancer. Do you have a minute to hear about our study?

If NO: Ok, sorry to bother you.

If YES: Thanks. Right now, very little is known about why people get prostate cancer. We are concerned, and are currently investigating biological factors linked to prostate cancer susceptibility.

- Right now, we are looking for people who have no cancer history to participate in the study as part of a healthy comparison group for our participants who have prostate cancer. Might you be interested in participating?
- If no or 'I had (something other than skin) cancer before' : Ok, thank you for your time. Good luck with your visit today.
- If yes, continue:
- The Study is entitled "Prostate Cancer Biomarker Resource" and is funded through the Department of Defense.
- Our objective is to provide our medical researchers with an epidemiological profile in the form of a questionnaire as well as biological samples. Thus, should you choose to participate you will first be asked to sign an informed consent form, take part in a 45minute interview and to provide a small sample of blood, urine, saliva, and toenail clippings.
- I would just like you to know that all information is kept strictly confidential. There is no information listed on the questionnaire or biologic specimen to reveal your identity. Additionally, joining the study is completely voluntary and will be of no direct benefit to you, but could help us develop better methods for understanding, diagnoses and treatment of prostate cancer. Such information is invaluable for both present and future patients. Would you like to participate?
- If YES: Administer control screening form.

If person tells of previous cancer diagnosis: I am sorry I wasn't so clear earlier, we are looking to enroll people with no cancer history. Thank you very much for your time and best of luck with your visit today.

If person meets eligibility criteria: It will take about 45 minutes for me to explain the study, have you sign the consent forms, and collect your biological samples. There is also a 45 minute interview that we could do here at GU if you have time or over the phone at your convenience. If we complete the interview here the whole thing would take under two hours. There would be no follow up. It would be just a one-time commitment. Do you have time today? If not, when do you plan on returning to the clinic? (Agree on a time to meet. Otherwise hand person brochure and point out

contact info on the back. Ask them to please call when they know their schedule). See you soon.

- If person declines at any time: Can I ask why you aren't interested? (find out age, race, smoking and drinking history as well as level of education) Thank you for your time best of luck with your visit today.

Molecular Epidemiology of Prostate Cancer (Case/Control)

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TABLE OF CONTENTS

Date of Interview MM DD YYYY	Time of Interview _____ ☐ 1 AM _____ ☐ 2 PM

Interviewer	Interviewer Signature

Study ID/ Site ID	LCC Number

MRN	Control? Yes_____ No_____

Reviewers initials	Date reviewed MM DD YYYY
Coders initials	Dated coded MM DD YYYY
First Entry initials	Date entered MM DD YYYY
Second entry initials	Date entered MM DD YYYY

Samples Collected	ID label
Blood ☐ ___ yellow ___ red ___ green ___ purple	
Mouthwash ☐	
Urine ☐	
Toenail ☐	
Tissue ☐	
Other ☐	

Your answers to the following questions are very important to us. Please answer them as truthfully as possible. Also, please remember that you do not have to answer any question that makes you feel uncomfortable.

A. IDENTIFIER SHEET

A1. What is your name? _____ / _____ / _____
First Middle Last

A2. Could your medical records be under a different name? If so, what name?

_____ / _____ / _____
First Middle Last

A3. What is your date of birth? ___ ___ / ___ ___ / ___ ___ ___ ___
MM DD YYYY

A4. What is your address?

_____
Street Apt. No.

_____ ___ ___ ___ ___ ___ - ___ ___ ___ ___
City State Zip Code

_____
Country

A5. What is your telephone number? Home: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Work: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Ext. ___ ___ ___ ___

Email _____

A6. Is there someone at a different address that would be able to help us contact you in the future?

_____ _____
Name Relationship to person

_____ _____
Street Apt. No.

_____ ___ ___ ___ ___ ___ ___ / ___ ___ ___ ___
City State Zip code

Home Telephone Number: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Work Telephone Number: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Ext. ___ ___ ___ ___

Email _____

IDENTIFIER SHEET ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

B. DEMOGRAPHIC INFORMATION

Now I would like to ask you some general information about yourself.

B1. What is your marital status?

( )1 Widowed
( )2 Married or living as married
( )3 Divorced
( )4 Separated
( )5 Single, never married

B2. Which of these categories best describes you?

( )1 White
( )2 Black or African American
( )3 Asian
( )4 Native Hawaiian or Other Pacific Islander
( )5 Other Specify_____

B3. What country or continent were you born in?

( )1 United States ( )2 Africa ( )3 Europe
( )4 Caribbean/West Indies ( )5 Asia ( )6 South America
( )7 Middle East ( )8 Canada ( )9 Australia
( )10 United Kingdom ( )11 Central America ( )12 Other_____

B4. If you moved from here, at what age did you move?_____

B5. What was the highest level of education you completed (don't read choices).

( )1 Less than 8th grade ( )2 Less than high school ( )3 High school graduate
( )4 Less than 4 years of college ( )5 College (4 years completed)
( )6 Graduate/professional coursework or degree

B6. In what religion were you raised?

( )1 Protestant ( )2 Catholic ( )3 Muslim
( )4 Jewish ( )5 None ( )6 Other Specify _____

If Jewish, are you Ashkenazi? _____yes _____no

B7. What is your current level of household income per year (read choices)?

( )1 Less than $25,000
( )2 $25,001 - $50,000
( )3 $50,001 - $100,000
( )4 $100,001- $150,000
( )5 Greater that $150,000
( )8 Don't know

B8. How many people are currently supported in your household? ____ ____

DEMOGRAPHIC INFO ( )1 Very Good ( )2 Good ( )3 Fair ( )4 Poor

C. MEDICATIONS

C1. Now I have some questions about any prescription medication you may have taken.

Drugs	C1.Have you ever taken (DRUG)?	C2. In what year did you first take (DRUG)?	C3. For how long did you take (DRUG)?	C4. How often did you take (DRUG) per day or per week?
a. Propecia used to treat baldness?	YES ..... 1 → NO ..... 2 (b)	____	__ MONTHS ..... 1 YEARS 2	__ PER DAY ..... 1 PER WEEK 2
b. Proscar or fenasteride used to treat prostate disease?	YES ..... 1 → NO ..... 2 (c)	____	__ MONTHS ..... 1 YEARS 2	__ PER DAY ..... 1 PER WEEK 2
c. Luprone or Zolodex used to treat prostate disease?	YES ..... 1 → NO ..... 2 (d)	____	__ MONTHS ..... 1 YEARS 2	__ PER DAY ..... 1 PER WEEK 2
d. Flutamide also called Eulexin; or Nilandron; or Casodex used to treat prostate disease?	YES ..... 1 → NO ..... 2 (e)	____	__ MONTHS ..... 1 YEARS 2	__ PER DAY ..... 1 PER WEEK 2
e. Urinary Obstruction Control Drugs. (Calcium Channel Blockers) (eg: Calan, Isoptin, Covera-HS, Varelen, Cardene, Adalat, Procardia, Cardura, Hytrin, Flomax,)	YES ..... 1 → NO ..... 2 (f)	____	__ MONTHS 1 YEARS 2	__ PER DAY .... 1 PER WEEK . 2
f. Viagra, Cialis, Levitra.	YES ..... 1 → NO 2 (C7)	____	__ MONTHS 1 YEARS 2	__ PER DAY .... 1 PER WEEK . 2

C2. Now I have some questions about supplements and other drugs some men take.

OTHER DRUGS AND SUPPLEMENTS	C5. Did you ever take (SUPPLEMENT)?	C6. In what year did you start to take (SUPPLEMENT)?	C7. How long did you take (SUPPLEMENT)?	C8. How often did you take (SUPPLEMENT) per day or per week?
a. DES (Diethyl stilbesterol)	YES.....1 → NO .....2 (b)	____	__ MONTHS....1 YEARS.....2	__ PER DAY 1 PER WEEK 2
b. Prostate Healthcare Drugs (ex: PC SPES, Saw Palmetto, Dayto, Homimex, Yoshimba, Damiana leave) Which one?____	YES ..... 1 → NO ..... 2(c)	____	__ MONTHS....1 YEARS.....2	__ PER DAY 1 PER WEEK 2
c. Lasix	YES ..... 1→ NO ..... 2(d)	____	__ MONTHS....1 YEARS.....2	__ PER DAY 1 PER WEEK 2
d. Lycopene	YES ..... 1 → NO ..... 2(e)	____	__ MONTHS....1 YEARS.....2	__ PER DAY 1 PER WEEK 2
e. Selenium	YES ..... 1 →	____	__ MONTHS....1	__ PER DAY 1

	NO ..... 2 (f)		YEARS.....2	PER WEEK 2
f. Vitamin E	YES ..... 1 → NO ..... 2(g)	|__|__|__|__|	|__| MONTHS....1 YEARS.....2	|__| PER DAY 1 PER WEEK 2
g. Body Building or performance enhancing steroids.(DHEA, 19-Nor/androstenedione) Which one?_____	YES ..... 1 → NO ..... 2(h)	|__|__|__|__|	|__| MONTHS....1 YEARS.....2	|__| PER DAY 1 PER WEEK 2
h. Statins or Cholersterol lowering drugs (ex. Lipitor, Zocor, Mevacor) Which one?_____	YES ..... 1 → NO ..... 2 (i)	|__|__|__|__|	|__| MONTHS....1 YEARS.....2	|__| PER DAY 1 PER WEEK 2
i. Cox-2 Inhibitors (Celebrex, Vioxx, Bextra)	YES ..... 1 → NO ..... 2 (j)	|__|__|__|__|	|__| MONTHS....1 YEARS.....2	|__| PER DAY 1 PER WEEK 2
j.Multivitamin. Which one(s)? _____ _____	YES ..... 1 → NO ..... 2 ()	|__|__|__|__	|__| MONTHS....1 YEARS.....2	|__| PER DAY 1 PER WEEK 2
k. Other Vitamins. Which one(s)? _____ _____	YES ..... 1 → NO ..... 2 ()	|__|__|__|__	|__| MONTHS....1 YEARS.....2	|__| PER DAY 1 PER WEEK 2

C3. Have you ever taken non-steroidal anti-inflammatory drugs (NSAIDs) such as Aspirin, Bufferin, Excedrin, Advil, Motrin, Nasproxsyn, and Ibuprofen (Tylenol is not an NSAID)?

( )$_0$ No (Skip to D) ( )$_1$ Occasionally (Skip to D) ( )$_2$ Weekly (Skip to D) ( )$_3$ Daily

C4. For what reason did you take NSAIDs?

( )$_0$ Headache ( )$_1$ Heart disease ( )$_2$ Stroke
( )$_3$ Arthritis ( )$_4$ Other_____(please specify)

C5. If you have taken NSAIDs on a daily basis, I would like to ask you about these periods during different times of your life. (Fill in table below)

Action	Period 1	Period 2	Period 3	Period 4	Period 5
a. In what year did you start taking these drugs?					
b. How many or how much did you take per day?	_____ ( )pills ( )mg	_____ ( )pills ( )mg	_____ ( )pills ( )mg	_____ ( )pills ( )mg	_____ ( )pills ( )mg
c.Which type or brand did you use?	_____	_____	_____	_____	_____
d. Did you continue to take this, stop or Δ your pattern for	( )$_0$ continued ( )$_1$ stopped ( )$_2$ pattern Δ	( )$_0$ continued ( )$_1$ stopped ( )$_2$ pattern Δ	( )$_0$ continued ( )$_1$ stopped ( )$_2$ pattern Δ	( )$_0$ continued ( )$_1$ stopped ( )$_2$ pattern Δ	( )$_0$ continued ( )$_1$ stopped ( )$_2$ pattern Δ

more than 6 months?					
e. Year you stopped taking NSAIDS or Δ your pattern for >6 months?	_____ If this is a Δ of pattern, ⇒C2a	_____ If this is a Δ of pattern, ⇒C3a	_____ If this is a Δ of pattern, ⇒C4a	_____ If this is a Δ of pattern, ⇒C5a	_____
f. Did you start NSAIDS again?	( )$_0$ no ⇒C6 ( )$_1$ yes ⇒C2a	( )$_0$ no ⇒C6 ( )$_1$ yes ⇒C2a	( )$_0$ no ⇒C6 ( )$_1$ yes ⇒C2a	( )$_0$ no ⇒C6 ( )$_1$ yes ⇒C2a	( )$_0$ no ( )$_1$ yes

C6. Have you taken any other prescription or non-prescription medications within the last year?

( )$_0$ No **(Skip to D)** ( )$_1$ Yes

C7. Which ones?

Name of Medication	Date began?	Date finished?	Reason for taking?	Notes

MEDICATIONS ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

D. SMOKING HISTORY

Now I have some questions about smoking.

D1. Have you ever smoked a total of 100 cigarettes or more in your lifetime?

( )$_0$ No **(Skip to E1)** ( )$_1$ Yes

D2. Did you ever smoke cigarettes regularly, at least one cigarette per day for six months or longer?

( )$_0$ No **(Skip to E1)** ( )$_1$ Yes

D3. How old were you when you first started smoking regularly? |__|__|

AGE STARTED

D4. Do you smoke cigarettes regularly now?

( )$_0$ No ( )$_1$ Yes **(Skip to D6)**

D5. How old were you when you stopped smoking regularly? |__|__|

AGE STOPPED

D6. In total, how many years have you smoked or did you smoke regularly (please subtract out years you did not smoke)?

|__|__|
YEARS

D7. Thinking about all the years when you smoked regularly, how many cigarettes did you usually smoke in a day?

|__|__|__|
CIGARETTES/DAY

D8. During your childhood, until you were 18, did anyone in your home smoke? (do not include this if smoking was done only outside the home). ( )0 No (skip to D10) ( )1 Yes

D9. How many people smoked in your home during your childhood? _____

D10. As an adult, does/did your spouse or partner or anyone else smoke in your home? (do not include this if smoking is/was done only outside the home). ( )0 No ( )1 Yes

D11. How many people smoked in your home during your adulthood? _____

D12. Do/Did you work in a place where co-workers smoked in your immediate area? ( )0 No ( )1 Yes

D13. For how many years were you working at a job where people smoked regularly in your immediate work area _____

SMOKING HISTORY ( )1 Very Good ( )2 Good ( )3 Fair ( )4 Poor

E. ALCOHOL HISTORY

E1. Did you ever drink any alcohol beverages, such as beer, wine or hard liquor, on a regular basis, that is, at least once a week for 6 months or longer?

( )0 No **(Skip to F1)** ( )1 Yes

E2. How old were you when you started drinking regularly? |__|__|
AGE STARTED

E3. Do you still drink regularly now? ( )0 No ( )1 Yes **(Skip to E5)**

E4. How old were you when you stopped drinking regularly? |__|__|
AGE STOPPED

E5. In total, for how many years have you or did you drink regularly? Please subtract out the years when you didn't drink regularly.

|__|__|
YEARS

E6. On the average, after age 25, how many (ALCOHOLIC BEVERAGE) did you drink per week?	E7. How many years did you drink (ALCOHOLIC BEVERAGE) regularly?

DRINKS	YEARS
1. .....Cans or Bottles of Beer |__|__|__|	|__|__|
2. ..... Glasses of Wine |__|__|__|	|__|__|
4. ..... Shots of hard liquor |__|__|__|	|__|__|

ALCOHOL HISTORY ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

F. OCCUPATIONAL HISTORY

We would like some information about the types of jobs you had **for the longest period of time.**

F1. What was the complete title of this job?_____

F2. Was this position a full-time or part-time job? (Full-time is 35 hours or more per week)
( )$_0$ Full-time
( )$_1$ Part-time

F3. What type of business or industry was this; that is what did this employer make or do? Please be as specific as possible._____

F4. What year did you begin this job and what year did you stop? ___/___ - ___/___
mo. yr mo. Yr

F5. What are/were your usual activities in this job?
_____

OCCUPATIONAL HISTORY ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

G. BODY SIZE/ ANTHROPOMETRY

G1. How tall are you? \|__\|__\| \|__\|__\| or \|__\|__\|
FT INCHES CM

DON'T KNOW----------988

G2. When you were about 8-9 years old, compared to other boys your age, were you ....?

Short	1
Somewhat short	2
Average height	3
Somewhat tall or	4
Tall?	5
DON'T KNOW	8

G3. When you were about 20-25 years old, compared to other men your age, were you ....?

Short	1
Somewhat short	2
Average height	3
Somewhat tall or	4
Tall?	5
DON'T KNOW	8

At what age did you reach your adult height? _____years

G4. After age 25, what has been your usual weight? |__|__|__| or |__|__|
LBS KG

DON'T KNOW 998

G5. Have you lost weight in the last 5 years? ( )0 No ( )1 Yes **(Skip to G8)**

G6. How much weight did you lose? |__|__|__| (IF LT 10 LBS GO TO G8)
LBS

G7. In the past 5 years, did you lose this weight without trying? ( )0 No ( )1 Yes

IN G8-G9, ASK EACH AGE GROUP ENDING WITH CURRENT AGE GROUP

	Age group				In the past year (prior to diagnosis)
	In 2nd to 4th grade	20-29 yrs old	40-49 yrs old	60-69 yrs old	
G8. When you were (AGE GROUP), compared with other males in the same age group were you ...?					
.....Very thin	 1	 1	 1	 1	 1
.....Somewhat thin	 2	 2	 2	 2	 2
..... Average	 3	 3	 3	 3	 3
.....Somewhat heavy	 4	 4	 4	 4	 4
..... Very heavy	 5	 5	 5	 5	 5
.....DON'T KNOW	 8	 8	 8	 8	 8
.....NOT APPLICABLE	 0	 0	 0	 0	 0
G9. What was your average weight at/in (AGE GROUP)?	|__|__|__| LBS	|__|__|__| LBS	|__|__|__| LBS	|__|__|__| LBS	|__|__|__| LBS
.....DON'T KNOW	998	998	998	998	998

G10. As an adult, what was your highest weight? |__|__|__| or |__|__|
LBS KG

G11. At what age did you first reach this highest weight? |__|__|
AGE

G12. For how many years or months were you at this highest weight? |__|__| MONTHS 1
YEARS 2

G13. When you gain weight, where on your body do you mainly tend to add the weight?
( )$_0$ don't gain weight
( )$_1$ around the waist and stomach
( )$_2$ around the hips and thighs
( )$_3$ around the chest and shoulders
( )$_4$ equally all over
( )$_5$ other (specify) _____

G14. Interviewer will ask: I would now like to measure your waist circumference (use standardized measurements- waist is belly button, hips are hip bone)

Waist circumference (cm)

First		Second		Difference	Tolerance	Third
|__|__|__|.|__|	|__|__|__|.|__|	|__|__|__|.|__|	2.0	|__|__|__|.|__|		

G15. Interviewer will ask: I would now like to measure your hip circumference.

Hip circumference (cm)

First		Second		Difference	Tolerance	Third
|__|__|__|.|__|	|__|__|__|.|__|	|__|__|__|.|__|	2.0	|__|__|__|.|__|		

G16. How would you describe your chest hair density? ( )$_0$ thick ( )$_1$ medium ( )$_2$ thin ( )$_3$ no hairs

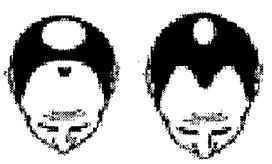
G17. Have you experienced any permanent hair loss from your scalp since you were twenty years old? ( )$_0$ No ( )$_1$ Yes

G18. If yes, at what age did the hair loss begin? __ __ years

G19. Interviewer: Please indicate hair thickness ( )$_0$ thick ( )$_1$ medium ( )$_2$ thin ( )$_3$ no hairs

G20. Interviewer: Please indicate hair pattern on dome
( )$_0$ no evident loss
( )$_1$ some loss
( )$_2$ patterned baldness
( )$_3$ few hairs
( )$_4$ no hairs

Some Loss



Patterned Baldness

G21. Have you ever used any hair growth products? ( )$_0$ No ( )$_1$ Yes

G22. Are you using a wig or toupee? ( )$_0$ No ( )$_1$ Yes

BODY SIZE/ANTHROPOMETRY ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

H. MEDICAL HISTORY

Now I am going to ask some questions about your health.

H1. Has a doctor ever told you that you had any of the following diseases? FOR EACH *YES* RESPONSE ASK I2. FOR EACH *NO* RESPONSE GO THE NEXT DISEASE				H2. IF YES Please tell me how old you were when the disease was (first) diagnosed.
	YES	NO		AGE
a.....Peptic ulcer	1	0	(b)	a. |___|___|
b. ..... Liver cirrhosis	1	0	(c)	b. |___|___|
c..... Other liver diseases	1	0	(d)	c. |___|___|
d. .....Hepatitis B	1	0	(e)	g. |___|___|
e.....Hepatitis C	1	0	(I3)	h. |___|___|

H3. Have you ever been told by a doctor that you have diabetes or sugar diabetes?
( )$_0$ No
( )$_1$ Yes

H4. At what age did your doctor first tell you this? __ __ years

H5. Are you now taking insulin?
( )$_0$ No **(Skip to H.8)**
( )$_1$ Yes

H6. At what age did you begin to take insulin? __ __ years

H7. For what reason do you take insulin? _____

H8. Are you now taking pills to lower you blood sugar? These are sometimes called oral agents or oral hypoglycemic agents?
( )$_0$ No **(Skip to I)** ( )$_1$ Yes

H9. At what age did you begin to take hypoglycemic agents? ___ years

H10. For what reason do you take hypoglycemic agents? _____

MEDICAL HISTORY ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

I. PROSTATE CANCER SCREENING HISTORY/UROLOGIC HEALTH

Now I'd like to ask you some questions about your urologic health.

Screening History

I1. Do you know the approximate date of your most recent examination (PSA test, DRE) for prostate cancer?
____/____/_____ _____ Don't remember (___ Never had examination (skip to I13)

I2. Was this examination performed by: _____your physician $_0$
_____a new physician who you did not know previously $_1$
_____in a free prostate cancer screening program $_2$

I3. Was the prostate exam done because you were experiencing any prostate-related symptoms (e.g., urinary control, pain)? ___yes$_1$ ____no$_0$ ____don't know$_8$

I4. Was your Digital Rectal Examination abnormal? ____yes$_1$ ____no$_0$ ____don't know$_8$

I5. Were you told that your PSA was elevated? ____yes$_1$ ____no$_0$ (skip to I8) ____don't know$_8$

I6. If so, what was your PSA value? _____(don't know=888)

I7. Did you follow up with further testing? ____yes$_1$ ____no$_0$

I8. Before this last exam , have you ever had an abnormal exam in the past (meaning that your doctor thought there was something that needed to be checked out further)? ____yes$_1$ ____no$_0$ ____don't know$_8$_____Never had exam before this last one$_9$.

I9. [IF YES] Have you had a biopsy previously? _____yes$_1$ ____no$_0$ ____don't know$_8$

a. Biopsy type	Diagnosis	Date	Hospital	Doctor
_____	_____	___/___/_____	_____	_____
_____	_____	___/___/_____	_____	_____
_____	_____	___/___/_____	_____	_____

I10. How often do you get checked out for prostate cancer?

_____every 3-6 months$_0$
_____annually$_1$
_____every 2 years$_2$
_____less often$_3$
_____don't know$_8$

I11. Approximately how many times would you say you have been checked for prostate cancer in your lifetime?
(This would include the PSA and/or DRE) _____(Don't know=888)

I12. Have you ever been screened in a free, mass screening program? ____yes$_1$ ____no$_0$

Urologic Health/History

I13. During a typical night, how many times do you wake up to urinate? *(For cases, please ask about a typical night during the 12 months prior to the prostate cancer diagnosis)*

( )$_0$ never (Skip to I15)
( )$_1$ once (Skip to I15)
( )$_2$ twice
( )$_3$ three times
( )$_4$ more than three times

I14. How old were you when you first began waking to urinate more than once a night on a regular basis?

___ ___ years

I15. Did a doctor ever tell you that you had:	Yes/No	How old were you when you were diagnosed?
a. an enlarged prostate or benign prostatic hypertrophy	( )$_0$ No ( )$_1$ Yes ( )$_8$ Don't know	
b. an inflamed prostate or prostatitis	( )$_0$ No ( )$_1$ Yes ( )$_8$ Don't know	
c. some other problem or disorder related to the urinary tract (specify) _____	( )$_0$ No ( )$_1$ Yes ( )$_8$ Don't know	
d. Some other problem or disorder related to the prostate (specify) _____	( )$_0$ No ( )$_1$ Yes ( )$_8$ Don't know	

I16. Have you ever had any prostate surgery?
( )$_0$ No **(Skip to I19)**
( )$_1$ Yes

I17. How many prostate surgeries have you had? _____

J18.	Year of surgery	Hospital name	City	State
a.				
b.				
c.				

I19. Were you ever treated by a doctor for a urinary tract infection since the age of 25?
( )$_0$ No
( )$_1$ Yes

I20. How old were you when your doctor first told you that you had a urinary tract infection?
___ ___ years

I21. How many times have you been diagnosed with a UTI?_____

I22. Have you had a vasectomy, that is a sterilization operation for men?
( )$_0$ No **(Skip to I24)**
( )$_1$ Yes

I23. How old were you when you had a vasectomy? ___ ___ years

I24. Were you circumcised? *Circumcision: The surgical removal of the foreskin of the penis.*
( )$_0$ No **(Skip to J)**
( )$_1$ Yes

I25. At what age were you circumcised?
( )$_1$ newborn
( )$_2$ other (specify in years) _____

PROSTATE HISTORY ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

J. FAMILY MEDICAL HISTORY

J1. Has anyone in your family that is related to you by blood, ever been told he had Benign Prostatic Hyperplasia or an enlarged prostate? Include your sons, grandsons, father, paternal grandfather, maternal grandfather and brothers. ( )$_0$ No ( )$_1$ Yes

J2. If yes, at what age was it diagnosed?

Relative			Age at diagnosis (approximately) DK= 888
a	Brother(s)	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
b	Father	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
c	Son (s)	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
d	Maternal Grandfather	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
e	Paternal Grandfather	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
f	Other _____(specify)	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	

J3. Has anyone in your family that is related to you by blood, ever been told he had prostate cancer? Include your sons, grandsons, father, paternal grandfather, maternal grandfather, brothers.

( )$_0$ No **(Skip to J5)** ( )$_1$ Yes

J4. If yes, at what age was it diagnosed?

Relative			Age at diagnosis (approximately) DK= 888
a	Brother(s)	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
b	Father	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
c	Son (s)	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
d	Maternal Grandfather	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
e	Paternal Grandfather	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
f	Other _____(specify)	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	

J5. Has any member of your family that is related to you by blood ever been told that she had breast cancer? Including your daughter, mother, sister, grandmothers. ( )$_0$ No **(Skip to J7)**

( )$_1$ Yes

J6. If yes, at what age was it diagnosed?

Relative			Age at diagnosis (approximately) DK= 888
a	Daughter	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
b	Mother	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
c	Sister	( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	

d	Maternal Grandmother ( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
e	Paternal Grandmother ( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	
f	Other _____(specify) ( )$_0$ No ( )$_1$ Yes ( )$_8$ DK	

J7. Have any members of your family that are related to you by blood ever been told that they had ovarian cancer? Please include your mother, daughter, and maternal and paternal grandmothers.

J8. If yes, at what age was it diagnosed?

Relative		Age at diagnosis (approximately) DK= 888
a	Daughter ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
b	Mother ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
c	Sister ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
d	Maternal Aunt ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
e	Paternal Grandmother ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
f	Other _____(specify) ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	

J9. Have any members of your family that are related to you by blood ever been told that they had endometrial cancer? Please include your mother, daughter, sisters and maternal and paternal grandmothers. ( )$_0$ No **(Skip to K)** ( )$_1$ Yes

J10. If yes, at what age was it diagnosed?

Relative		Age at diagnosis (approximately) DK= 888
a	Daughter ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
b	Mother ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
c	Sister(s) ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
d	Maternal Aunt ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
e	Paternal Grandmother ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	
f	Other _____(specify) ( )$_0$ No ( )$_1$ Yes ( )$_8$ D.K.	

FAMILY MEDICAL HISTORY ( )$_1$ Very Good ( )$_2$ Good ( )$_3$ Fair ( )$_4$ Poor

K. PHYSICAL ACTIVITY/EXERCISE

Now, we are going to ask you about your levels of physical activity at different times in your life.

	a. Last year	b. Age 13-19	c. 20s	d. 30s	e. 40s	f. 50s+
K1. Did you participate in any routine physical activity for at least 20 minutes at a time that either made you sweat or increased your heart rate?	0 No 1 Yes	0 No 1 Yes	0 No 1 Yes	0 No 1 Yes	0 No 1 Yes	0 No 1 Yes
K2. What intensity level was your usual activity?	1 Moderate 2 Vigorous	1 Moderate 2 Vigorous	1Moderate 2 Vigorous	1 Moderate 2 Vigorous	1 Moderate 2 Vigorous	1 Moderate 2 Vigorous
K3. How often did you participate in this physical activity?	1 Less than 1x/week 2 1x/week 3 more than 1x/week	1 Less than 1x/week 2 1x/week 3 more than 1x/week	1 Less than 1x/week 2 1x/week 3 more than 1x/week	1 Less than 1x/week 2 1x/week 3 more than 1x/week	1 Less than 1x/week 2 1x/week 3 more than 1x/week	1 Less than 1x/week 2 1x/ week 3 more than 1x/week

PHYSICAL ACTIVITY ( )1 Very Good ( )2 Good ( )3 Fair ( )4 Poor

Section L (Sexual history) is self-administered, and the person will be given 20 min to complete this section.

SITE ID:____________________

L. SEXUAL HISTORY/HEALTH (self administered)

L1. At what age did you experience puberty (voice change, growth of pubic hair)? __ __ years

L2. How old were you when you first had sexual intercourse? __ __ years

	In your teens	In your 20's	In your 30's	In your 40's	In your 50's	In your 60's	In your 70's
L3.When you were (age group) with how many different partners did you have intercourse?	( )$_0$ 0 ( )$_1$ 1 ( )$_2$ 2 ( )$_3$ 3-4 ( )$_4$ 5-9 ( )$_5$ 10-19 ( )$_6$ 20-39 ( )$_7$ 40 or more	( )$_0$ 0 ( )$_1$ 1 ( )$_2$ 2 ( )$_3$ 3-4 ( )$_4$ 5-9 ( )$_5$ 10-19 ( )$_6$ 20-39 ( )$_7$ 40 or more	( )$_0$ 0 ( )$_1$ 1 ( )$_2$ 2 ( )$_3$ 3-4 ( )$_4$ 5-9 ( )$_5$ 10-19 ( )$_6$ 20-39 ( )$_7$ 40 or more	( )$_0$ 0 ( )$_1$ 1 ( )$_2$ 2 ( )$_3$ 3-4 ( )$_4$ 5-9 ( )$_5$ 10-19 ( )$_6$ 20-39 ( )$_7$ 40 or more	( )$_0$ 0 ( )$_1$ 1 ( )$_2$ 2 ( )$_3$ 3-4 ( )$_4$ 5-9 ( )$_5$ 10-19 ( )$_6$ 20-39 ( )$_7$ 40 or more	( )$_0$ 0 ( )$_1$ 1 ( )$_2$ 2 ( )$_3$ 3-4 ( )$_4$ 5-9 ( )$_5$ 10-19 ( )$_6$ 20-39 ( )$_7$ 40 or more	( )$_0$ 0 ( )$_1$ 1 ( )$_2$ 2 ( )$_3$ 3-4 ( )$_4$ 5-9 ( )$_5$ 10-19 ( )$_6$ 20-39 ( )$_7$ 40 or more
L4.If you think back to when you were (age group), and you think about the period of time in that decade when you had sexual intercourse, how often would you say you had sexual intercourse per month or per year?	______ times per ( ) month$_1$ ( ) year$_2$	______ times per ( ) month$_1$ ( ) year$_2$	______ times per ( ) month$_1$ ( ) year$_2$	______ times per ( ) month$_1$ ( ) year$_2$	______ times per ( ) month$_1$ ( ) year$_2$	______ times per ( ) month$_1$ ( ) year$_2$	______ times per ( ) month$_1$ ( ) year$_2$

L5. How many live-born children have you fathered? Do not include any stepchildren, foster children, or adopted children. __ __ __ **(If zero, skip to L7)**

L6. How old were you when your first child was born? __ __ years

L7. Have you ever tried to conceive a child for one year or more without success? ( )$_0$ No ( )$_1$ Yes

SITE ID:_____

L8. Did a doctor ever say that you had a problem that might be related to your difficulty in conceiving a child? If so, what was the problem? ( )$_0$ Low sperm count ( )$_1$ Low sperm motility ( )$_2$ Impotence ( )$_3$ Other _____(specify)

L9. Have you ever used condoms (rubbers)? ( )$_0$ No **(If No, skip to L13)** ( )$_1$ Yes

L10 Not counting the times that you were trying to conceive a child, how often did you use condoms? ( )$_0$ Rarely ( )$_1$ Sometimes ( )$_2$ Always

L11. Before one year ago, did you usually use condoms (rubbers)? ( )$_0$ No ( )$_1$ Yes

L12. Not counting the past year, for how many years did you use condoms (rubbers)?_____ YEARS

For the next question, please think about any sexually transmitted diseases that you may have contracted during your life.

L13.	Did a doctor ever tell you that you had:	Yes/No	How old were you when you were first diagnosed?	How many times altogether have you had the disease?
a.	Gonorrhea	( )$_0$ No ( )$_1$ Yes		
b.	Syphilis	( )$_0$ No ( )$_1$ Yes		
c.	Genital Warts	( )$_0$ No ( )$_1$ Yes		
d.	Genital Herpes	( )$_0$ No ( )$_1$ Yes		
e.	Other sexually transmitted disease (specify)	( )$_0$ No ( )$_1$ Yes		
f.	Other sexually transmitted disease (specify)	( )$_0$ No ( )$_1$ Yes		

This completes our interview. I would like to now take the samples and I want to thank you very much for the time you have spent in answering my questions today.

May we contact you again later if we need to clarify any of the information you have provided?
( )0 No ( )1 Yes

Time ended: ___ ___ : ___ ___ ( )1 AM
( )2 PM

M. ADMINISTRATIVE INFORMATION

M1. Date form completed ___ ___ / ___ ___ / ___ ___ ___ ___

M2. Name of interviewer _____/_____/_____

M3. Interviewer ID Number: ___ ___

M4. Interviewer's Signature: _____

N. INTERVIEWER REMARKS

N1. Interview was conducted:
( )1 In the clinic_____
( )2 General Clinical Research Center
( )3 Over the phone
( )4 Other (specify)_____

N2. Respondent's cooperation was:
( )1 Very good
( )2 Good
( )3 Fair
( )4 Poor

N3. The overall quality of the interview was:
( )1 Very good
( )2 Good
( )3 Fair
( )4 Poor

N4. Did any of the following occur during the interview?

a.	R did not know enough information regarding the topics.	( )0 No	( )1 Yes
b.	R did not want to be more specific.	( )0 No	( )1 Yes
c.	R did not understand or speak English well.	( )0 No	( )1 Yes
d.	R was upset or depressed.	( )0 No	( )1 Yes
e.	R had poor hearing or speech.	( )0 No	( )1 Yes
f.	R was confused by frequent interruptions.	( )0 No	( )1 Yes
g.	R was emotionally unstable.	( )0 No	( )1 Yes

h.	Others helped with the answers.	( )0 No	( )1 Yes
i.	R required a lot of probing	( )0 No	( )1 Yes
j.	Patient was reserved	( )0 No	( )1 Yes
k.	R was physically ill	( )0 No	( )1 Yes
l.	Other, (specify) _____	( )0 No	( )1 Yes

N5. Comments/Remarks:

_____

_____

_____

_____

_____

_____

_____

NATIONAL INSTITUTES OF HEALTH

Diet History Questionnaire

GENERAL INSTRUCTIONS

- **Answer each question as best you can. Estimate if you are not sure. A guess is better than leaving a blank.**
- **Use only a black ball-point pen. Do not use a pencil or felt-tip pen. Do not fold, staple, or tear the pages.**
- **Put an X in the box next to your answer.**
- **If you make any changes, cross out the incorrect answer and put an X in the box next to the correct answer. Also draw a circle around the correct answer.**
- **If you mark NEVER, NO, or DON'T KNOW for a question, please follow any arrows or instructions that direct you to the next question.**

BEFORE TURNING THE PAGE, PLEASE COMPLETE THE FOLLOWING QUESTIONS.

Today's date:

MONTH	DAY		YEAR
☐ Jan	___	___	☐ 2002
☐ Feb	☐0	☐0	☐ 2003
☐ Mar	☐1	☐1	☐ 2004
☐ Apr	☐2	☐2	☐ 2005
☐ May	☐3	☐3	☐ 2006
☐ Jun		☐4	
☐ Jul		☐5	
☐ Aug		☐6	
☐ Sep		☐7	
☐ Oct		☐8	
☐ Nov		☐9	
☐ Dec			

In what month were you born?

- ☐ Jan
- ☐ Feb
- ☐ Mar
- ☐ Apr
- ☐ May
- ☐ Jun
- ☐ Jul
- ☐ Aug
- ☐ Sep
- ☐ Oct
- ☐ Nov
- ☐ Dec

In what year were you born?

19 ___ ___

☐0	☐0
☐1	☐1
☐2	☐2
☐3	☐3
☐4	☐4
☐5	☐5
☐6	☐6
☐7	☐7
☐8	☐8
☐9	☐9

Are you male or female?

- ☐ Male
- ☐ Female

BAR CODE LABEL OR SUBJECT ID HERE

___ ___ ___ ___ ___ ___ ___ ___

1. Over the past 12 months, how often did you drink **tomato juice** or **vegetable juice**?

☐ NEVER (GO TO QUESTION 2)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

1a. Each time you drank **tomato juice** or **vegetable juice**, how much did you usually drink?

☐ Less than ¾ cup (6 ounces)
☐ ¾ to 1¼ cups (6 to 10 ounces)
☐ More than 1¼ cups (10 ounces)

2. Over the past 12 months, how often did you drink **orange juice** or **grapefruit juice?**

☐ NEVER (GO TO QUESTION 3)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

2a. Each time you drank **orange juice** or **grapefruit juice**, how much did you usually drink?

☐ Less than ¾ cup (6 ounces)
☐ ¾ to 1¼ cups (6 to 10 ounces)
☐ More than 1¼ cups (10 ounces)

3. Over the past 12 months, how often did you drink **other 100% fruit juice** or **100% fruit juice mixtures** (such as apple, grape, pineapple, or others)?

☐ NEVER (GO TO QUESTION 4)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

3a. Each time you drank **other fruit juice** or **fruit juice mixtures**, how much did you usually drink?

☐ Less than ¾ cup (6 ounces)
☐ ¾ to 1½ cups (6 to 12 ounces)
☐ More than 1½ cups (12 ounces)

Question 4 appears in the next column

Over the past 12 months...

4. How often did you drink other **fruit drinks** (such as cranberry cocktail, Hi-C, lemonade, or Kool-Aid, diet or regular)?

☐ NEVER (GO TO QUESTION 5)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

4a. Each time you drank **fruit drinks**, how much did you usually drink?

☐ Less than 1 cup (8 ounces)
☐ 1 to 2 cups (8 to 16 ounces)
☐ More than 2 cups (16 ounces)

4b. How often were your fruit drinks **diet** or **sugar-free drinks**?

☐ Almost never or never
☐ About ¼ of the time
☐ About ½ of the time
☐ About ¾ of the time
☐ Almost always or always

5. How often did you drink **milk as a beverage** (NOT in coffee, NOT in cereal)? (Please include chocolate milk and hot chocolate.)

☐ NEVER (GO TO QUESTION 6)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

5a. Each time you drank **milk as a beverage**, how much did you usually drink?

☐ Less than 1 cup (8 ounces)
☐ 1 to 1½ cups (8 to 12 ounces)
☐ More than 1½ cups (12 ounces)

5b. What kind of **milk** did you usually drink?

☐ Whole milk
☐ 2% fat milk
☐ 1 % fat milk
☐ Skim, nonfat, or ½% fat milk
☐ Soy milk
☐ Rice milk
☐ Other

Question 6 appears on the next page

Over the <u>past 12 months</u>...

6. How often did you drink **meal replacement, energy, or high-protein beverages** such as Instant Breakfast, Ensure, Slimfast, Sustacal or others?

☐ NEVER (GO TO QUESTION 7)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

6a. Each time you drank **meal replacement beverages**, how much did you usually drink?

☐ Less than 1 cup (8 ounces)
☐ 1 to 1½ cups (8 to 12 ounces)
☐ More than 1½ cups (12 ounces)

7. Over the past 12 months, did you drink **soft drinks, soda,** or **pop**?

☐ NO (GO TO QUESTION 8)

☐ YES

7a. How often did you drink **soft drinks, soda,** or **pop IN THE SUMMER**?

☐ NEVER

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

7b. How often did you drink **soft drinks, soda,** or **pop DURING THE REST OF THE YEAR**?

☐ NEVER

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

7c. Each time you drank **soft drinks, soda,** or **pop,** how much did you usually drink?

☐ Less than 12 ounces or less than 1 can or bottle
☐ 12 to 16 ounces or 1 can or bottle
☐ More than 16 ounces or more than 1 can or bottle

7d. How often were these soft drinks, soda, or pop **diet** or **sugar-free**?

☐ Almost never or never
☐ About ¼ of the time
☐ About ½ of the time
☐ About ¾ of the time
☐ Almost always or always

7e. How often were these soft drinks, soda, or pop **caffeine-free**?

☐ Almost never or never
☐ About ¼ of the time
☐ About ½ of the time
☐ About ¾ of the time
☐ Almost always or always

8. Over the <u>past 12 months</u>, did you drink **beer**?

☐ NO (GO TO QUESTION 9)

☐ YES

8a. How often did you drink **beer IN THE SUMMER**?

☐ NEVER

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

8b. How often did you drink **beer DURING THE REST OF THE YEAR**?

☐ NEVER

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

8c. Each time you drank **beer**, how much did you usually drink?

☐ Less than a 12-ounce can or bottle
☐ 1 to 3 12-ounce cans or bottles
☐ More than 3 12-ounce cans or bottles

Question 8 appears in the next column

Question 9 appears on the next page

Over the past 12 months...

9. How often did you drink **wine** or **wine coolers**?

☐ NEVER (GO TO QUESTION 10)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

9a. Each time you drank **wine** or **wine coolers**, how much did you usually drink?

☐ Less than 5 ounces or less than 1 glass
☐ 5 to 12 ounces or 1 to 2 glasses
☐ More than 12 ounces or more than 2 glasses

10. How often did you drink **liquor** or **mixed drinks**?

☐ NEVER (GO TO QUESTION 11)

☐ 1 time per month or less
☐ 2–3 times per month
☐ 1–2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2–3 times per day
☐ 4–5 times per day
☐ 6 or more times per day

10a. Each time you drank **liquor** or **mixed drinks**, how much did you usually drink?

☐ Less than 1 shot of liquor
☐ 1 to 3 shots of liquor
☐ More than 3 shots of liquor

11. Over the past 12 months, did you eat **oatmeal, grits, or other cooked cereal?**

☐ NO (GO TO QUESTION 12)

☐ YES

11a. How often did you eat **oatmeal, grits,** or **other cooked cereal IN THE WINTER**?

☐ NEVER

☐ 1–6 times per winter
☐ 7–11 times per winter
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

11b. How often did you eat **oatmeal, grits,** or **other cooked cereal DURING THE REST OF THE YEAR**?

☐ NEVER

☐ 1–6 times per year
☐ 7–11 times per year
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

11c. Each time you ate **oatmeal, grits,** or **other cooked cereal,** how much did you usually eat?

☐ Less than ¾ cup
☐ ¾ to 1¼ cups
☐ More than 1¼ cups

12. How often did you eat **cold cereal**?

☐ NEVER (GO TO QUESTION 13)

☐ 1–6 times per year
☐ 7–11 times per year
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

12a. Each time you ate **cold cereal**, how much did you usually eat?

☐ Less than 1 cup
☐ 1 to 2½ cups
☐ More than 2½ cups

12b. How often was the cold cereal you ate **Total, Product 19,** or **Right Start**?

☐ Almost never or never
☐ About ¼ of the time
☐ About ½ of the time
☐ About ¾ of the time
☐ Almost always or always

12c. How often was the cold cereal you ate **All Bran, Fiber One, 100% Bran,** or **Bran Buds?**

☐ Almost never or never
☐ About ¼ of the time
☐ About ½ of the time
☐ About ¾ of the time
☐ Almost always or always

Question 12 appears in the next column

Question 13 appears on the next page

Over the <u>past 12 months</u>...

12d. How often was the cold cereal you ate **some other bran** or **fiber cereal** (such as Cheerios, Shredded Wheat, Raisin Bran, Bran Flakes, Grape-Nuts, Granola, Wheaties, or Healthy Choice)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

12e. How often was the cold cereal you ate any **other type of cold cereal** (such as Corn Flakes, Rice Krispies, Frosted Flakes, Special K, Froot Loops, Cap'n Crunch, or others)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

12f. Was **milk** added to your cold cereal?

- ☐ NO (GO TO QUESTION 13)
- ☐ YES

12g. What kind of **milk** was usually added?

- ☐ Whole milk
- ☐ 2% fat milk
- ☐ 1% fat milk
- ☐ Skim, nonfat, or ½% fat milk
- ☐ Soy milk
- ☐ Rice milk
- ☐ Other

12h. Each time **milk was added to your cold cereal**, how much was usually added?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

13. How often did you eat **applesauce**?

- ☐ NEVER (GO TO QUESTION 14)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 14 appears in the next column

13a. Each time you ate **applesauce**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

14. How often did you eat **apples**?

- ☐ NEVER (GO TO QUESTION 15)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

14a. Each time you ate **apples**, how many did you usually eat?

- ☐ Less than 1 apple
- ☐ 1 apple
- ☐ More than 1 apple

15. How often did you eat **pears** (fresh, canned, or frozen)?

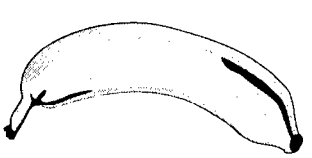
- ☐ NEVER (GO TO QUESTION 16)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

15a. Each time you ate **pears**, how many did you usually eat?

- ☐ Less than 1 pear
- ☐ 1 pear
- ☐ More than 1 pear

16. How often did you eat **bananas?**

- ☐ NEVER (GO TO QUESTION 17)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day



Question 17 appears on the next page

Over the past 12 months...

16a. Each time you ate **bananas**, how many did you usually eat?

- ☐ Less than 1 banana
- ☐ 1 banana
- ☐ More than 1 banana

17. How often did you eat **dried fruit**, such as prunes or raisins (not including dried apricots)?

- ☐ NEVER (GO TO QUESTION 18)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

17a. Each time you ate **dried fruit**, how much did you usually eat (not including dried apricots)?

- ☐ Less than 2 tablespoons
- ☐ 2 to 5 tablespoons
- ☐ More than 5 tablespoons

18. Over the past 12 months, did you eat **peaches, nectarines,** or **plums**?

- ☐ NO (GO TO QUESTION 19)
- ☐ YES

18a. How often did you eat **fresh peaches, nectarines**, or **plums WHEN IN SEASON**?

- ☐ NEVER

- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

18b. How often did you eat **peaches, nectarines,** or **plums** (fresh, canned, or frozen) **DURING THE REST OF THE YEAR**?

- ☐ NEVER

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

18c. Each time you ate **peaches, nectarines,** or **plums,** how much did you usually eat?

- ☐ Less than 1 fruit or less than ½ cup
- ☐ 1 to 2 fruits or ½ to ¾ cup
- ☐ More than 2 fruits or more than ¾ cup

19. How often did you eat **grapes**?

- ☐ NEVER (GO TO QUESTION 20)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

19a. Each time you ate **grapes**, how much did you usually eat?

- ☐ Less than ½ cup or less than 10 grapes
- ☐ ½ to 1 cup or 10 to 30 grapes
- ☐ More than 1 cup or more than 30 grapes

20. Over the past 12 months, did you eat **cantaloupe**?

- ☐ NO (GO TO QUESTION 21)
- ☐ YES

20a. How often did you eat **fresh cantaloupe WHEN IN SEASON**?

- ☐ NEVER

- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

20b. How often did you eat **fresh** or **frozen cantaloupe DURING THE REST OF THE YEAR**?

- ☐ NEVER

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 19 appears in the next column

Question 21 appears on the next page

Over the past 12 months...

20c. Each time you ate **cantaloupe**, how much did you usually eat?

- ☐ Less than ¼ melon or less than ½ cup
- ☐ ¼ melon or ½ to 1 cup
- ☐ More than ¼ melon or more than 1 cup

21. Over the past 12 months, did you eat **melon, other than cantaloupe** (such as watermelon or honeydew)?

- ☐ NO (GO TO QUESTION 22)
- ☐ YES

21a. How often did you eat **fresh melon, other than cantaloupe** (such as watermelon or honeydew) **WHEN IN SEASON**?

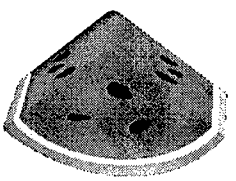
- ☐ NEVER
- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

21b. How often did you eat **fresh** or **frozen melon, other than cantaloupe** (such as watermelon or honeydew) **DURING THE REST OF THE YEAR**?

- ☐ NEVER
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

21c. Each time you ate **melon other than cantaloupe**, how much did you usually eat?

- ☐ Less than ½ cup or 1 small wedge
- ☐ ½ to 2 cups or 1 medium wedge
- ☐ More than 2 cups or 1 large wedge



Question 22 appears in the next column

22. Over the past 12 months, did you eat **strawberries**?

- ☐ NO (GO TO QUESTION 23)
- ☐ YES

22a. How often did you eat **fresh strawberries WHEN IN SEASON**?

- ☐ NEVER
- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

22b. How often did you eat **fresh** or **frozen strawberries DURING THE REST OF THE YEAR**?

- ☐ NEVER
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

22c. Each time you ate **strawberries**, how much did you usually eat?

- ☐ Less than ¼ cup or less than 3 berries
- ☐ ¼ to ¾ cup or 3 to 8 berries
- ☐ More than ¾ cup or more than 8 berries

23. Over the past 12 months, did you eat **oranges, tangerines, or tangelos**?

- ☐ NO (GO TO QUESTION 24)
- ☐ YES

23a. How often did you eat **fresh oranges, tangerines, or tangelos WHEN IN SEASON**?

- ☐ NEVER
- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 24 appears on the next page

Over the past 12 months...

23b. How often did you eat **oranges, tangerines, or tangelos** (fresh or canned) **DURING THE REST OF THE YEAR?**

- ☐ NEVER
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

23c. Each time you ate **oranges, tangerines, or tangelos,** how many did you usually eat?

- ☐ Less than 1 fruit
- ☐ 1 fruit
- ☐ More than 1 fruit

24. Over the past 12 months, did you eat **grapefruit?**

- ☐ NO (GO TO QUESTION 25)
- ☐ YES

24a. How often did you eat **fresh grapefruit WHEN IN SEASON?**

- ☐ NEVER
- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

24b. How often did you eat **grapefruit** (fresh or canned) **DURING THE REST OF THE YEAR?**

- ☐ NEVER
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

24c. Each time you ate **grapefruit**, how much did you usually eat?

- ☐ Less than ½ grapefruit
- ☐ ½ grapefruit
- ☐ More than ½ grapefruit

25. How often did you eat **other kinds of fruit?**

- ☐ NEVER (GO TO QUESTION 26)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

25a. Each time you ate **other kinds of fruit**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to ¾ cup
- ☐ More than ¾ cup

26. How often did you eat **COOKED greens** (such as spinach, turnip, collard, mustard, chard, or kale)?

- ☐ NEVER (GO TO QUESTION 27)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

26a. Each time you ate **COOKED greens**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

27. How often did you eat **RAW greens** (such as spinach, turnip, collard, mustard, chard, or kale)? *(We will ask about lettuce later.)*

- ☐ NEVER (GO TO QUESTION 28)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

27a. Each time you ate **RAW greens**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

Question 25 appears in the next column

Question 28 appears on the next page

Over the past 12 months...

28. How often did you eat **coleslaw**?

- ☐ NEVER (GO TO QUESTION 29)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

28a. Each time you ate **coleslaw**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to ¾ cup
- ☐ More than ¾ cup

29. How often did you eat **sauerkraut** or **cabbage** (other than coleslaw)?

- ☐ NEVER (GO TO QUESTION 30)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

29a. Each time you ate **sauerkraut** or **cabbage**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to 1 cup
- ☐ More than 1 cup

30. How often did you eat **carrots** (fresh, canned, or frozen)?

- ☐ NEVER (GO TO QUESTION 31)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

30a. Each time you ate **carrots**, how much did you usually eat?

- ☐ Less than ¼ cup or less than 2 baby carrots
- ☐ ¼ to ½ cup or 2 to 5 baby carrots
- ☐ More than ½ cup or more than 5 baby carrots

Question 31 appears in the next column

31. How often did you eat **string beans** or **green beans** (fresh, canned, or frozen)?

- ☐ NEVER (GO TO QUESTION 32)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

31a. Each time you ate **string beans** or **green beans**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

32. How often did you eat **peas** (fresh, canned, or frozen)?

- ☐ NEVER (GO TO QUESTION 33)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

32a. Each time you ate **peas**, how much did you usually eat?

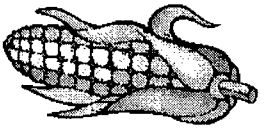
- ☐ Less than ¼ cup
- ☐ ¼ to ¾ cup
- ☐ More than ¾ cup

33. Over the past 12 months, did you eat **corn**?

- ☐ NO (GO TO QUESTION 34)
- ☐ YES

33a. How often did you eat **fresh corn WHEN IN SEASON**?

- ☐ NEVER
- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day



Question 34 appears on the next page

Over the past 12 months...

33b. How often did you eat **corn** (fresh, canned, or frozen) **DURING THE REST OF THE YEAR?**

- ☐ NEVER
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

33c. Each time you ate **corn**, how much did you usually eat?

- ☐ Less than 1 ear or less than ½ cup
- ☐ 1 ear or ½ to 1 cup
- ☐ More than 1 ear or more than 1 cup

34. Over the past 12 months, how often did you eat **broccoli** (fresh or frozen)?

- ☐ NEVER (GO TO QUESTION 35)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

34a. Each time you ate **broccoli**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to 1 cup
- ☐ More than 1 cup

35. How often did you eat **cauliflower** or **Brussels sprouts** (fresh or frozen)?

- ☐ NEVER (GO TO QUESTION 36)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

35a. Each time you ate **cauliflower** or **Brussels sprouts**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to ½ cup
- ☐ More than ½ cup

Question 36 appears in the next column

36. How often did you eat mixed **vegetables**?

- ☐ NEVER (GO TO QUESTION 37)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

36a. Each time you ate **mixed vegetables**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

37. How often did you eat **onions**?

- ☐ NEVER (GO TO QUESTION 38)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

37a. Each time you ate **onions**, how much did you usually eat?

- ☐ Less than 1 slice or less than 1 tablespoon
- ☐ 1 slice or 1 to 4 tablespoons
- ☐ More than 1 slice or more than 4 tablespoons

38. Now think about all the **cooked vegetables** you ate in the past 12 months and how they were prepared. How often were your vegetables **COOKED WITH** some sort of **fat**, including oil spray? *(Please do not include potatoes.)*

- ☐ NEVER (GO TO QUESTION 39)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 39 appears on the next page

Over the past 12 months...

38a. Which fats were usually added to your vegetables **DURING COOKING**? *(Please do not include potatoes. **Mark all that apply.**)*

- ☐ Margarine (including low-fat)
- ☐ Butter (including low-fat)
- ☐ Lard, fatback, or bacon fat
- ☐ Olive oil
- ☐ Corn oil
- ☐ Canola or rapeseed oil
- ☐ Oil spray, such as Pam or others
- ☐ Other kinds of oils
- ☐ None of the above

39. Now, thinking again about all the **cooked vegetables** you ate in the past 12 months, how often was some sort of fat, sauce, or dressing added **AFTER COOKING OR AT THE TABLE**? *(Please do not include potatoes.)*

- ☐ NEVER (GO TO QUESTION 40)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1–2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 times per day
- ☐ 3 or more times per day

39a. Which fats, sauces, or dressings were usually added **AFTER COOKING OR AT THE TABLE**? *(Please do not include potatoes. **Mark all that apply.**)*

- ☐ Margarine (including low-fat)
- ☐ Butter (including low-fat)
- ☐ Lard, fatback, or bacon fat
- ☐ Salad dressing
- ☐ Cheese sauce
- ☐ White sauce
- ☐ Other

39b. If margarine, butter, lard, fatback, or bacon fat was added to your cooked vegetables **AFTER COOKING OR AT THE TABLE**, how much did you usually add?

- ☐ Did not usually add these
- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

39c. If salad dressing, cheese sauce, or white sauce was added to your cooked vegetables **AFTER COOKING OR AT THE TABLE**, how much did you usually add?

- ☐ Did not usually add these
- ☐ Less than 1 tablespoon
- ☐ 1 to 3 tablespoons
- ☐ More than 3 tablespoons

Question 40 appears in the next column

40. Over the past 12 months, how often did you eat **sweet peppers** (green, red, or yellow)?

- ☐ NEVER (GO TO QUESTION 41)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

40a. Each time you ate **sweet peppers**, how much did you usually eat?

- ☐ Less than ⅛ pepper
- ☐ ⅛ to ¼ pepper
- ☐ More than ¼ pepper

41. Over the past 12 months, did you eat **fresh tomatoes** (including those in salads)?

- ☐ NO (GO TO QUESTION 42)
- ☐ YES

41a. How often did you eat **fresh tomatoes** (including those in salads) **WHEN IN SEASON**?

- ☐ NEVER
- ☐ 1–6 times per season
- ☐ 7–11 times per season
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

41b. How often did you eat **fresh tomatoes** (including those in salads) **DURING THE REST OF THE YEAR**?

- ☐ NEVER
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

41c. Each time you ate **fresh tomatoes**, how much did you usually eat?

- ☐ Less than ¼ tomato
- ☐ ¼ to ½ tomato
- ☐ More than ½ tomato

Question 42 appears on the next page

Over the <u>past 12 months</u>...

42. How often did you eat **lettuce salads** (with or without other vegetables)?

☐ NEVER (GO TO QUESTION 43)

☐ 1–6 times per year	☐ 2 times per week
☐ 7–11 times per year	☐ 3–4 times per week
☐ 1 time per month	☐ 5–6 times per week
☐ 2–3 times per month	☐ 1 time per day
☐ 1 time per week	☐ 2 or more times per day

42a. Each time you ate **lettuce salads**, how much did you usually eat?

☐ Less than ¼ cup
☐ ¼ to 1 /4 cups
☐ More than 1 /4 cups

43. How often did you eat **salad dressing** (including low-fat) on salads?

☐ NEVER (GO TO QUESTION 44)

☐ 1–6 times per year	☐ 2 times per week
☐ 7–11 times per year	☐ 3–4 times per week
☐ 1 time per month	☐ 5–6 times per week
☐ 2–3 times per month	☐ 1 time per day
☐ 1 time per week	☐ 2 or more times per day

43a. Each time you ate **salad dressing** on salads, how much did you usually eat?

☐ Less than 2 tablespoons
☐ 2 to 4 tablespoons
☐ More than 4 tablespoons

44. How often did you eat **sweet potatoes** or **yams**?

☐ NEVER (GO TO QUESTION 45)

☐ 1–6 times per year	☐ 2 times per week
☐ 7–11 times per year	☐ 3–4 times per week
☐ 1 time per month	☐ 5–6 times per week
☐ 2–3 times per month	☐ 1 time per day
☐ 1 time per week	☐ 2 or more times per day

44a. Each time you ate **sweet potatoes** or **yams**, how much did you usually eat?

☐ 1 small potato or less than ¼ cup
☐ 1 medium potato or ¼ to ¾ cup
☐ 1 large potato or more than ¾ cup

Question 45 appears in the next column

45. How often did you eat **French fries, home fries, hash browned potatoes**, or **tater tots**?

☐ NEVER (GO TO QUESTION 46)

☐ 1–6 times per year	☐ 2 times per week
☐ 7–11 times per year	☐ 3–4 times per week
☐ 1 time per month	☐ 5–6 times per week
☐ 2–3 times per month	☐ 1 time per day
☐ 1 time per week	☐ 2 or more times per day

45a. Each time you ate **French fries**, **home fries**, **hash browned potatoes**, or **tater tots** how much did you usually eat?

☐ Less than 10 fries or less than ½ cup
☐ 10 to 25 fries or ½ to 1 cup
☐ More than 25 fries or more than 1 cup

46. How often did you eat **potato salad**?

☐ NEVER (GO TO QUESTION 47)

☐ 1–6 times per year	☐ 2 times per week
☐ 7–11 times per year	☐ 3–4 times per week
☐ 1 time per month	☐ 5–6 times per week
☐ 2–3 times per month	☐ 1 time per day
☐ 1 time per week	☐ 2 or more times per day

46a. Each time you ate **potato salad**, how much did you usually eat?

☐ Less than ½ cup
☐ ½ to 1 cup
☐ More than 1 cup

47. How often did you eat **baked, boiled,** or **mashed potatoes**?

☐ NEVER (GO TO QUESTION 48)

☐ 1–6 times per year	☐ 2 times per week
☐ 7–11 times per year	☐ 3–4 times per week
☐ 1 time per month	☐ 5–6 times per week
☐ 2–3 times per month	☐ 1 time per day
☐ 1 time per week	☐ 2 or more times per day

47a. Each time you ate **baked, boiled,** or **mashed potatoes**, how much did you usually eat?

☐ 1 small potato or less than ½ cup
☐ 1 medium potato or ½ to 1 cup
☐ 1 large potato or more than 1 cup

Question 48 appears on the next page

Over the <u>past 12 months</u>...

47b. How often was **sour cream** (including low-fat) added to your potatoes, **EITHER IN COOKING OR AT THE TABLE**?

- ☐ Almost never or never (GO TO QUESTION 47d)
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

47c. Each time **sour cream** was added to your potatoes, how much was usually added?

- ☐ Less than 1 tablespoon
- ☐ 1 to 3 tablespoons
- ☐ More than 3 tablespoons

47d. How often was **margarine** (including low-fat) added to your potatoes, **EITHER IN COOKING OR AT THE TABLE**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

47e. How often was **butter** (including low-fat) added to your potatoes, **EITHER IN COOKING OR AT THE TABLE**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

47f. Each time **margarine** or **butter** was added to your potatoes, how much was usually added?

- ☐ Never added
- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

47g. How often was cheese or cheese sauce added to your potatoes, EITHER IN COOKING OR AT THE TABLE?

- ☐ Almost never or never (GO TO QUESTION 48)
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 48 appears in the next column

47h. Each time **cheese** or **cheese sauce** was added to your potatoes, how much was usually added?

- ☐ Less than 1 tablespoon
- ☐ 1 to 3 tablespoons
- ☐ More than 3 tablespoons

48. How often did you eat **salsa**?

- ☐ NEVER (GO TO QUESTION 49)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

48a. Each time you ate **salsa**, how much did you usually eat?

- ☐ Less than 1 tablespoon
- ☐ 1 to 5 tablespoons
- ☐ More than 5 tablespoons

49. How often did you eat **catsup**?

- ☐ NEVER (GO TO QUESTION 50)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

49a. Each time you ate **catsup**, how much did you usually eat?

- ☐ Less than 1 teaspoon
- ☐ 1 to 6 teaspoons
- ☐ More than 6 teaspoons

50. How often did you eat **stuffing, dressing,** or **dumplings**?

- ☐ NEVER (GO TO QUESTION 51)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

50a. Each time you ate **stuffing, dressing,** or **dumplings**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

Question 51 appears on the next page

Over the <u>past 12 months</u>...

51. How often did you eat **chili**?

- ☐ NEVER (GO TO QUESTION 52)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

51a. Each time you ate **chili**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 3/4 cups
- ☐ More than 1 3/4 cups

52. How often did you eat **Mexican foods** (such as tacos, tostados, burritos, tamales, fajitas, enchiladas, quesadillas, and chimichangas)?

- ☐ NEVER (GO TO QUESTION 53)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

52a. Each time you ate **Mexican foods**, how much did you usually eat?

- ☐ Less than 1 taco, burrito, etc.
- ☐ 1 to 2 tacos, burritos, etc.
- ☐ More than 2 tacos, burritos, etc.

53. How often did you eat **cooked dried beans** (such as baked beans, pintos, kidney, blackeyed peas, lima, lentils, soybeans, or refried beans)? *(Please don't include bean soups or chili.)*

- ☐ NEVER (GO TO QUESTION 54)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

53a. Each time you ate **beans**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

53b. How often were the beans you ate **refried beans, beans prepared with any type of fat**, or **with meat added**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

54. How often did you eat **other kinds of vegetables**?

- ☐ NEVER (GO TO QUESTION 55)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

54a. Each time you ate **other kinds of vegetables**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to ½ cup
- ☐ More than ½ cup

55. How often did you eat **rice** or **other cooked grains** (such as bulgur, cracked wheat, or millet)?

- ☐ NEVER (GO TO QUESTION 56)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

55a. Each time you ate **rice** or **other cooked grains**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 /2 cups
- ☐ More than 1 /2 cups

55b. How often was **butter, margarine**, or **oil** added to your rice **IN COOKING OR AT THE TABLE**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 54 appears in the next column

Question 56 appears on the next page

Over the <u>past 12 months</u>...

56. How often did you eat **pancakes, waffles,** or **French toast**?

- ☐ NEVER (GO TO QUESTION 57)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

56a. Each time you ate **pancakes, waffles,** or **French toast**, how much did you usually eat?

- ☐ Less than 1 medium piece
- ☐ 1 to 3 medium pieces
- ☐ More than 3 medium pieces

56b. How often was **margarine** (including low-fat) added to your pancakes, waffles, or French toast **AFTER COOKING OR AT THE TABLE**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

56c. How often was **butter** (including low-fat) added to your pancakes, waffles, or French toast **AFTER COOKING OR AT THE TABLE**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

56d. Each time **margarine** or **butter** was added to your pancakes, waffles, or French toast, how much was usually added?

- ☐ Never added
- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

56e. How often was **syrup** added to your pancakes, waffles, or French toast?

- ☐ Almost never or never (GO TO QUESTION 57)
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 57 appears in the next column

56f. Each time **syrup** was added to your pancakes, waffles, or French toast, how much was usually added?

- ☐ Less than 1 tablespoon
- ☐ 1 to 4 tablespoons
- ☐ More than 4 tablespoons

57. How often did you eat **lasagna, stuffed shells, stuffed manicotti, ravioli,** or **tortellini**? *(Please do not include spaghetti or other pasta.)*

- ☐ NEVER (GO TO QUESTION 58)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

57a. Each time you ate **lasagna, stuffed shells, stuffed manicotti, ravioli,** or **tortellini**, how much did you usually eat?

- ☐ Less than 1 cup
- ☐ 1 to 2 cups
- ☐ More than 2 cups

58. How often did you eat **macaroni and cheese**?

- ☐ NEVER (GO TO QUESTION 59)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

58a. Each time you ate **macaroni and cheese**, how much did you usually eat?

- ☐ Less than 1 cup
- ☐ 1 to 1 /2 cups
- ☐ More than 1 /2 cups

59. How often did you eat **pasta salad** or **macaroni salad**?

- ☐ NEVER (GO TO QUESTION 60)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 60 appears on the next page

Over the <u>past 12 months</u>...

59a. Each time you ate **pasta salad** or **macaroni salad**, how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

60. Other than the pastas listed in Questions 57, 58, and 59, how often did you eat **pasta, spaghetti**, or **other noodles**?

- ☐ NEVER (GO TO QUESTION 61)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

60a. Each time you ate **pasta, spaghetti, or other noodles**, how much did you usually eat?

- ☐ Less than 1 cup
- ☐ 1 to 3 cups
- ☐ More than 3 cups

60b. How often did you eat your pasta, spaghetti, or other noodles with **tomato sauce** or **spaghetti sauce made WITH meat**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

60c. How often did you eat your pasta, spaghetti, or other noodles with **tomato sauce** or **spaghetti sauce made WITHOUT meat**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

60d. How often did you eat your pasta, spaghetti, or other noodles with **margarine, butter, oil,** or **cream sauce**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 61 appears in the next column

61. How often did you eat **bagels** or **English muffins**?

- ☐ NEVER (GO TO INTRODUCTION TO QUESTION 62)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

61a. Each time you ate **bagels** or **English muffins**, how many did you usually eat?

- ☐ Less than 1 bagel or English muffin
- ☐ 1 bagel or English muffin
- ☐ More than 1 bagel or English muffin

61b. How often was **margarine** (including low-fat) added to your bagels or English muffins?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

61c. How often was **butter** (including low-fat) added to your bagels or English muffins?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

61d. Each time **margarine** or **butter** was added to your bagels or English muffins, how much was usually added?

- ☐ Never added
- ☐ Less than 1 teaspoon
- ☐ 1 to 2 teaspoons
- ☐ More than 2 teaspoons

61e. How often was **cream cheese** (including low-fat) spread on your bagels or English muffins?

- ☐ Almost never or never (GO TO INTRODUCTION TO QUESTION 62)
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Introduction to Question 62 appears on the next page

Over the <u>past 12 months</u>...

61f. Each time **cream cheese** was added to your bagels or English muffins, how much was usually added?

- ☐ Less than 1 tablespoon
- ☐ 1 to 2 tablespoons
- ☐ More than 2 tablespoons

The next questions ask about your intake of breads other than bagels or English muffins. First, we will ask about bread you ate as part of sandwiches only. Then we will ask about all other bread you ate.

62. How often did you eat **breads** or **rolls AS PART OF SANDWICHES** (including burger and hot dog rolls)?

- ☐ NEVER (GO TO QUESTION 63)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

62a. Each time you ate **breads** or **rolls AS PART OF SANDWICHES**, how many did you usually eat?

- ☐ 1 slice or ½ roll
- ☐ 2 slices or 1 roll
- ☐ More than 2 slices or more than 1 roll

62b. How often were the breads or rolls that you used for your sandwiches **white bread** (including burger and hot dog rolls)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

62c. How often was **mayonnaise** or **mayonnaise-type dressing** (including low-fat) added to your sandwich bread or rolls?

- ☐ Almost never or never (GO TO QUESTION 62e)
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 62e appears in the next column

Question 63 appears in the next column

62d. Each time **mayonnaise** or **mayonnaise-type dressing** was added to your sandwich breads or rolls, how much was usually added?

- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

62e. How often was **margarine** (including low-fat) added to your sandwich bread or rolls?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

62f. How often was **butter** (including low-fat) added to your sandwich bread or rolls?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

62g. Each time **margarine** or **butter** was added to your sandwich breads or rolls, how much was usually added?

- ☐ Never added
- ☐ Less than 1 teaspoon
- ☐ 1 to 2 teaspoons
- ☐ More than 2 teaspoons

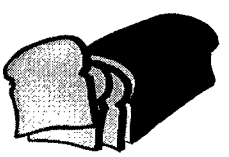
63. How often did you eat **breads** or **dinner rolls, NOT AS PART OF SANDWICHES**?

- ☐ NEVER (GO TO QUESTION 64)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

63a. Each time you ate **breads** or **dinner rolls, NOT AS PART OF SANDWICHES**, how much did you usually eat?

- ☐ 1 slice or 1 dinner roll
- ☐ 2 slices or 2 dinner rolls
- ☐ More than 2 slices or 2 dinner rolls



Question 64 appears on the next page

Over the past 12 months...

63b. How often were the breads or rolls you ate **white bread**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

63c. How often was **margarine** (including low-fat) added to your breads or rolls?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

63d. How often was **butter** (including low-fat) added to your breads or rolls?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

63e. Each time **margarine** or **butter** was added to your breads or rolls, how much was usually added?

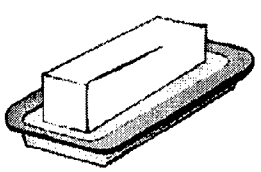
- ☐ Never added
- ☐ Less than 1 teaspoon
- ☐ 1 to 2 teaspoons
- ☐ More than 2 teaspoons

63f. How often was **cream cheese** (including low-fat) added to your breads or rolls?

- ☐ Almost never or never (GO TO QUESTION 64)
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

63g. Each time **cream cheese** was added to your breads or rolls, how much was usually added?

- ☐ Less than 1 tablespoon
- ☐ 1 to 2 tablespoons
- ☐ More than 2 tablespoons



Question 64 appears in the next column

64. How often did you eat **jam, jelly,** or **honey** on bagels, muffins, bread, rolls, or crackers?

- ☐ NEVER (GO TO QUESTION 65)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

64a. Each time you ate **jam, jelly,** or **honey**, how much did you usually eat?

- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

65. How often did you eat **peanut butter** or **other nut butter**?

- ☐ NEVER (GO TO QUESTION 66)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

65a. Each time you ate **peanut butter** or **other nut butter**, how much did you usually eat?

- ☐ Less than 1 tablespoon
- ☐ 1 to 2 tablespoons
- ☐ More than 2 tablespoons

66. How often did you eat **roast beef** or **steak IN SANDWICHES**?

- ☐ NEVER (GO TO QUESTION 67)
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

66a. Each time you ate **roast beef** or **steak IN SANDWICHES**, how much did you usually eat?

- ☐ Less than 1 slice or less than 2 ounces
- ☐ 1 to 2 slices or 2 to 4 ounces
- ☐ More than 2 slices or more than 4 ounces

Question 67 appears on the next page

Over the <u>past 12 months</u>...

67. How often did you eat **turkey** or **chicken COLD CUTS** (such as loaf, luncheon meat, turkey ham, turkey salami, or turkey pastrami)? *(We will ask about other turkey or chicken later.)*

- ☐ NEVER (GO TO QUESTION 68)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

67a. Each time you ate **turkey or chicken COLD CUTS**, how much did you usually eat?

- ☐ Less than 1 slice
- ☐ 1 to 3 slices
- ☐ More than 3 slices

68. How often did you eat **luncheon** or **deli-style ham**? *(We will ask about other ham later.)*

- ☐ NEVER (GO TO QUESTION 69)

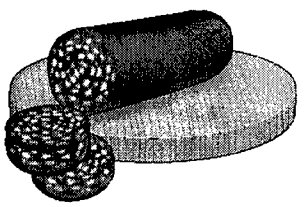
- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

68a. Each time you ate **luncheon** or **deli-style ham**, how much did you usually eat?

- ☐ Less than 1 slice
- ☐ 1 to 3 slices
- ☐ More than 3 slices

68b. How often was the luncheon or deli-style ham you ate **light**, **low-fat**, or **fat-free**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always



Question 69 appears in the next column

69. How often did you eat **other cold cuts** or **luncheon meats** (such as bologna, salami, corned beef, pastrami, or others, including low-fat)? *(Please do not include ham, turkey, or chicken cold cuts.)*

- ☐ NEVER (GO TO QUESTION 70)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

69a. Each time you ate **other cold cuts** or **luncheon meats**, how much did you usually eat?

- ☐ Less than 1 slice
- ☐ 1 to 3 slices
- ☐ More than 3 slices

69b. How often were the other cold cuts or luncheon meats you ate **light, low-fat**, or **fat-free cold cuts** or **luncheon meats**? *(Please do not include ham, turkey, or chicken cold cuts.)*

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

70. How often did you eat **canned tuna** (including in salads, sandwiches, or casseroles)?

- ☐ NEVER (GO TO QUESTION 71)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

70a. Each time you ate **canned tuna**, how much did you usually eat?

- ☐ Less than ¼ cup or less than 2 ounces
- ☐ ¼ to ½ cup or 2 to 3 ounces
- ☐ More than ½ cup or more than 3 ounces

70b. How often was the canned tuna you ate **water-packed tuna**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 71 appears on the next page

Over the <u>past 12 months</u>...

70c. How often was the canned tuna you ate **prepared with mayonnaise** or **other dressing** (including low-fat)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

71. How often did you eat **GROUND chicken** or **turkey**? *(We will ask about other chicken and turkey later.)*

- ☐ NEVER (GO TO QUESTION 72)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

71a. Each time you ate **GROUND chicken** or **turkey**, how much did you usually eat?

- ☐ Less than 2 ounces or less than ½ cup
- ☐ 2 to 4 ounces or ½ to 1 cup
- ☐ More than 4 ounces or more than 1 cup

72. How often did you eat **beef hamburgers** or **cheeseburgers**?

- ☐ NEVER (GO TO QUESTION 73)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

72a. Each time you ate **beef hamburgers** or **cheeseburgers**, how much did you usually eat?

- ☐ Less than 1 patty or less than 2 ounces
- ☐ 1 patty or 2 to 4 ounces
- ☐ More than 1 patty or more than 4 ounces

72b. How often were the beef hamburgers or cheeseburgers you ate made with **lean ground beef**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 73 appears in the next column

73. How often did you eat **ground beef in mixtures** (such as meatballs, casseroles, chili, or meatloaf)?

- ☐ NEVER (GO TO QUESTION 74)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

73a. Each time you ate **ground beef in mixtures**, how much did you usually eat?

- ☐ Less than 3 ounces or less than ½ cup
- ☐ 3 to 8 ounces or ½ to 1 cup
- ☐ More than 8 ounces or more than 1 cup

74. How often did you eat **hot dogs** or **frankfurters**? *(Please do not include sausages or vegetarian hot dogs.)*

- ☐ NEVER (GO TO QUESTION 75)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

74a. Each time you ate **hot dogs** or **frankfurters**, how many did you usually eat?

- ☐ Less than 1 hot dog
- ☐ 1 to 2 hot dogs
- ☐ More than 2 hot dogs

74b. How often were the hot dogs or frankfurters you ate **light** or **low-fat hot dogs**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 75 appears on the next page

Over the past 12 months...

75. How often did you eat beef mixtures such as **beef stew, beef pot pie, beef and noodles,** or **beef and vegetables**?

- ☐ NEVER (GO TO QUESTION 76)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

75a. Each time you ate **beef stew, beef pot pie, beef and noodles,** or **beef and vegetables,** how much did you usually eat?

- ☐ Less than 1 cup
- ☐ 1 to 2 cups
- ☐ More than 2 cups

76. How often did you eat **roast beef** or **pot roast**? *(Please do not include roast beef or pot roast in sandwiches.)*

- ☐ NEVER (GO TO QUESTION 77)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

76a. Each time you ate **roast beef** or **pot roast** (including in mixtures), how much did you usually eat?

- ☐ Less than 2 ounces
- ☐ 2 to 5 ounces
- ☐ More than 5 ounces

77. How often did you eat **steak** (beef)? *(Do not include steak in sandwiches)*

- ☐ NEVER (GO TO QUESTION 78)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

77a. Each time you ate **steak** (beef), how much did you usually eat?

- ☐ Less than 3 ounces
- ☐ 3 to 7 ounces
- ☐ More than 7 ounces

77b. How often was the steak you ate **lean steak**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

78. How often did you eat **pork** or **beef spareribs**?

- ☐ NEVER (GO TO QUESTION 79)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

78a. Each time you ate **pork** or **beef spareribs**, how much did you usually eat?

- ☐ Less than 4 ribs
- ☐ 4 to 12 ribs
- ☐ More than 12 ribs

79. How often did you eat **roast turkey, turkey cutlets,** or **turkey nuggets** (including in sandwiches)?

- ☐ NEVER (GO TO QUESTION 80)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

79a. Each time you ate **roast turkey, turkey cutlets,** or **turkey nuggets**, how much did you usually eat? *(Please note: 4 to 8 turkey nuggets = 3 ounces.)*

- ☐ Less than 2 ounces
- ☐ 2 to 4 ounces
- ☐ More than 4 ounces

80. How often did you eat **chicken** as part of **salads, sandwiches, casseroles, stews,** or **other mixtures**?

- ☐ NEVER (GO TO QUESTION 81)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 78 appears in the next column

Question 81 appears on the next page

Over the <u>past 12 months</u>...

80a. Each time you ate **chicken** as part of **salads, sandwiches, casseroles, stews,** or **other mixtures,** how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 /2 cups
- ☐ More than 1 /2 cups

81. How often did you eat **baked, broiled, roasted, stewed,** or **fried chicken** (including nuggets)? *(Please do not include chicken in mixtures.)*

- ☐ NEVER (GO TO QUESTION 82)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

81a. Each time you ate **baked, broiled, roasted, stewed,** or **fried chicken** (including nuggets), how much did you usually eat?

- ☐ Less than 2 drumsticks or wings, less than 1 breast or thigh, or less than 4 nuggets
- ☐ 2 drumsticks or wings, 1 breast or thigh, or 4 to 8 nuggets
- ☐ More than 2 drumsticks or wings, more than 1 breast or thigh, or more than 8 nuggets

81b. How often was the chicken you ate **fried chicken** (including deep fried) or **chicken nuggets**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

81c. How often was the chicken you ate **WHITE meat**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

81d. How often did you eat chicken **WITH skin**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 82 appears in the next column

82. How often did you eat **baked ham** or **ham steak**?

- ☐ NEVER (GO TO QUESTION 83)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

82a. Each time you ate **baked ham** or **ham steak**, how much did you usually eat?

- ☐ Less than 1 ounce
- ☐ 1 to 3 ounces
- ☐ More than 3 ounces

83. How often did you eat **pork** (including chops, roasts, and in mixed dishes)? *(Please do not include ham, ham steak, or sausage.)*

- ☐ NEVER (GO TO QUESTION 84)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

83a. Each time you ate **pork**, how much did you usually eat?

- ☐ Less than 2 ounces or less than 1 chop
- ☐ 2 to 5 ounces or 1 chop
- ☐ More than 5 ounces or more than 1 chop

84. How often did you eat **gravy** on meat, chicken, potatoes, rice, etc.?

- ☐ NEVER (GO TO QUESTION 85)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

84a. Each time you ate **gravy** on meat, chicken, potatoes, rice, etc., how much did you usually eat?

- ☐ Less than ⅛ cup
- ☐ ⅛ to ½ cup
- ☐ More than ½ cup

Question 85 appears on the next page

Over the <u>past 12 months</u>...

85. How often did you eat **liver** (all kinds) or **liverwurst**?

- ☐ NEVER (GO TO QUESTION 86)

☐ 1–6 times per year
☐ 7–11 times per year
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

85a. Each time you ate **liver** or **liverwurst**, how much did you usually eat?

☐ Less than 1 ounce
☐ 1 to 4 ounces
☐ More than 4 ounces

86. How often did you eat **bacon** (including low-fat)?

- ☐ NEVER (GO TO QUESTION 87)

☐ 1–6 times per year
☐ 7–11 times per year
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

86a. Each time you ate **bacon**, how much did you usually eat?

☐ Fewer than 2 slices
☐ 2 to 3 slices
☐ More than 3 slices

86b. How often was the bacon you ate **light, low-fat,** or **lean bacon**?

☐ Almost never or never
☐ About ¼ of the time
☐ About ½ of the time
☐ About ¾ of the time
☐ Almost always or always

87. How often did you eat **sausage** (including low-fat)?

- ☐ NEVER (GO TO QUESTION 88)

☐ 1–6 times per year
☐ 7–11 times per year
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

Question 88 appears in the next column

87a. Each time you ate **sausage**, how much did you usually eat?

☐ Less than 1 patty or 2 links
☐ 1 to 3 patties or 2 to 5 links
☐ More than 3 patties or 5 links

87b. How often was the sausage you ate **light, low-fat**, or **lean sausage**?

☐ Almost never or never
☐ About ¼ of the time
☐ About ½ of the time
☐ About ¾ of the time
☐ Almost always or always

88. How often did you eat **fish sticks** or **fried fish** (including fried seafood or shellfish)?

- ☐ NEVER (GO TO QUESTION 89)

☐ 1–6 times per year
☐ 7–11 times per year
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

88a. Each time you ate **fish sticks** or **fried fish**, how much did you usually eat?

☐ Less than 2 ounces or less than 1 fillet
☐ 2 to 7 ounces or 1 fillet
☐ More than 7 ounces or more than 1 fillet

89. How often did you eat **fish** or **seafood that was NOT FRIED** (including shellfish)?

- ☐ NEVER (GO TO INTRODUCTION TO QUESTION 90)

☐ 1–6 times per year
☐ 7–11 times per year
☐ 1 time per month
☐ 2–3 times per month
☐ 1 time per week
☐ 2 times per week
☐ 3–4 times per week
☐ 5–6 times per week
☐ 1 time per day
☐ 2 or more times per day

89a. Each time you ate eat **fish** or **seafood that was NOT FRIED**, how much did you usually eat?

☐ Less than 2 ounces or less than 1 fillet
☐ 2 to 5 ounces or 1 fillet
☐ More than 5 ounces or more than 1 fillet

Introduction to Question 90 appears on the next page

Over the past 12 months...

Now think about all the meat, poultry, and fish you ate in the past 12 months and how they were prepared.

90. How often was **oil, butter, margarine, or other fat** used to **FRY, SAUTE, BASTE, OR MARINATE** any meat, poultry, or fish you ate? *(Please do not include deep frying.)*

- ☐ NEVER (GO TO QUESTION 91)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

90a. Which of the following **fats** were regularly used to prepare your meat, poultry, or fish? ***(Mark all that apply.)***

- ☐ Margarine (including low-fat)
- ☐ Butter (including low-fat)
- ☐ Lard, fatback, or bacon fat
- ☐ Olive oil
- ☐ Corn oil
- ☐ Canola or rapeseed oil
- ☐ Oil spray, such as Pam or others
- ☐ Other kinds of oils
- ☐ None of the above

91. How often did you eat **tofu, soy burgers,** or **soy meat-substitutes**?

- ☐ NEVER (GO TO QUESTION 92)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

91a. Each time you ate **tofu, soy burgers,** or **soy meat-substitutes**, how much did you usually eat?

- ☐ Less than ¼ cup or less than 2 ounces
- ☐ ¼ to ½ cup or 2 to 4 ounces
- ☐ More than ½ cup or more than 4 ounces

Question 92 appears in the next column

92. Over the past 12 months, did you eat **soups**?

- ☐ NO (GO TO QUESTION 93)
- ☐ YES

92a. How often did you eat **soup DURING THE WINTER**?

- ☐ NEVER

- ☐ 1–6 times per winter
- ☐ 7–11 times per winter
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

92b. How often did you eat **soup DURING THE REST OF THE YEAR**?

- ☐ NEVER

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

92c. Each time you ate **soup**, how much did you usually eat?

- ☐ Less than 1 cup
- ☐ 1 to 2 cups
- ☐ More than 2 cups

92d. How often were the soups you ate **bean soups**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

92e. How often were the soups you ate **cream soups** (including chowders)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 93 appears on the next page

Over the <u>past 12 months</u>...

92f. How often were the soups you ate **tomato** or **vegetable soups**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

92g. How often were the soups you ate **broth soups** (including chicken) **with** or **without noodles** or **rice**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

93. How often did you eat **pizza**?

- ☐ NEVER (GO TO QUESTION 94)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

93a. Each time you ate **pizza**, how much did you usually eat?

- ☐ Less than 1 slice or less than 1 mini pizza
- ☐ 1 to 3 slices or 1 mini pizza
- ☐ More than 3 slices or more than 1 mini pizza

93b. How often did you eat pizza with **pepperoni, sausage**, or **other meat**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

94. How often did you eat **crackers**?

- ☐ NEVER (GO TO QUESTION 95)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

94a. Each time you ate **crackers**, how many did you usually eat?

- ☐ Fewer than 4 crackers
- ☐ 4 to 10 crackers
- ☐ More than 10 crackers

95. How often did you eat **corn bread** or **corn muffins**?

- ☐ NEVER (GO TO QUESTION 96)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

95a. Each time you ate **corn bread** or **corn muffins,** how much did you usually eat?

- ☐ Less than 1 piece or muffin
- ☐ 1 to 2 pieces or muffins
- ☐ More than 2 pieces or muffins

96. How often did you eat **biscuits**?

- ☐ NEVER (GO TO QUESTION 97)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

96a. Each time you ate **biscuits**, how many did you usually eat?

- ☐ Fewer than 1 biscuit
- ☐ 1 to 2 biscuits
- ☐ More than 2 biscuits

97. How often did you eat **potato chips, tortilla chips,** or **corn chips** (including low-fat, fat-free, or low-salt)?

- ☐ NEVER (GO TO QUESTION 98)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 95 appears in the next column

Question 98 appears on the next page

Over the past 12 months...

97a. Each time you ate **potato chips, tortilla chips,** or **corn chips**, how much did you usually eat?

- ☐ Fewer than 10 chips or less than 1 cup
- ☐ 10 to 25 chips or 1 to 2 cups
- ☐ More than 25 chips or more than 2 cups

97b. How often were the chips you ate **Wow chips** or other **chips made with fat substitute** (Olean or Olestra)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

97c. How often were the chips you ate other **low-fat** or **fat-free chips**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

98. How often did you eat **popcorn** (including low-fat)?

- ☐ NEVER (GO TO QUESTION 99)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

98a. Each time you ate **popcorn**, how much did you usually eat?

- ☐ Less than 2 cups, popped
- ☐ 2 to 5 cups, popped
- ☐ More than 5 cups, popped

99. How often did you eat **pretzels**?

- ☐ NEVER (GO TO QUESTION 100)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 100 appears in the next column

99a. Each time you ate **pretzels**, how many did you usually eat?

- ☐ Fewer than 5 average twists
- ☐ 5 to 20 average twists
- ☐ More than 20 average twists

100. How often did you eat **peanuts, walnuts, seeds,** or **other nuts**?

- ☐ NEVER (GO TO QUESTION 101)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

100a. Each time you ate **peanuts, walnuts, seeds,** or **other nuts**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to ½ cup
- ☐ More than ½ cup

101. How often did you eat **energy, high-protein**, or **breakfast bars** such as **Power Bars, Balance, Clif,** or **others**?

- ☐ NEVER (GO TO QUESTION 102)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

101a. Each time you ate **energy, high-protein**, or **breakfast bars**, how much did you usually eat?

- ☐ Less than 1 bar
- ☐ 1 bar
- ☐ More than 1 bar

102. How often did you eat **yogurt** (NOT including frozen yogurt)?

- ☐ NEVER (GO TO QUESTION 103)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 103 appears on the next page

Over the <u>past 12 months</u>...

102a. Each time you ate **yogurt**, how much did you usually eat?

- ☐ Less than ½ cup or less than 1 container
- ☐ ½ to 1 cup or 1 container
- ☐ More than 1 cup or more than 1 container

103. How often did you eat **cottage cheese** (including low-fat)?

- ☐ NEVER (GO TO QUESTION 104)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

103a. Each time you ate **cottage cheese**, how much did you usually eat?

- ☐ Less than ¼ cup
- ☐ ¼ to 1 cup
- ☐ More than 1 cup

104. How often did you eat **cheese** (including low-fat; including on cheeseburgers or in sandwiches or subs)?

- ☐ NEVER (GO TO QUESTION 105)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

104a. Each time you ate **cheese**, how much did you usually eat?

- ☐ Less than ½ ounce or less than 1 slice
- ☐ ½ to 1 /2 ounces or 1 slice
- ☐ More than 1 /2 ounces or more than 1 slice

104b. How often was the cheese you ate **light** or **low-fat cheese**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 105 appears in the next column

104c. How often was the cheese you ate **fat-free cheese**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

105. How often did you eat **frozen yogurt, sorbet,** or **ices** (including low-fat or fat-free)?

- ☐ NEVER (GO TO QUESTION 106)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

105a. Each time you ate **frozen yogurt, sorbet,** or **ices**, how much did you usually eat?

- ☐ Less than ½ cup or less than 1 scoop
- ☐ ½ to 1 cup or 1 to 2 scoops
- ☐ More than 1 cup or more than 2 scoops

106. How often did you eat **ice cream, ice cream bars,** or **sherbet** (including low-fat or fat-free)?

- ☐ NEVER (GO TO QUESTION 107)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

106a. Each time you ate **ice cream, ice cream bars,** or **sherbet**, how much did you usually eat?

- ☐ Less than ½ cup or less than 1 scoop
- ☐ ½ to 1 /2 cups or 1 to 2 scoops
- ☐ More than 1 /2 cups or more than 2 scoops

106b. How often was the ice cream you ate **light, low-fat,** or **fat-free ice cream** or **sherbet**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 107 appears on the next page

Over the <u>past 12 months</u>...

107. How often did you eat **cake** (including low-fat or fat-free)?

- ☐ NEVER (GO TO QUESTION 108)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

107a. Each time you ate **cake**, how much did you usually eat?

- ☐ Less than 1 medium piece
- ☐ 1 medium piece
- ☐ More than 1 medium piece

107b. How often was the cake you ate **light, low-fat,** or **fat-free cake**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

108. How often did you eat **cookies** or **brownies** (including low-fat or fat-free)?

- ☐ NEVER (GO TO QUESTION 109)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

108a. Each time you ate **cookies** or **brownies**, how much did you usually eat?

- ☐ Less than 2 cookies or 1 small brownie
- ☐ 2 to 4 cookies or 1 medium brownie
- ☐ More than 4 cookies or 1 large brownie

108b. How often were the cookies or brownies you ate **light, low-fat,** or **fat-free cookies** or **brownies**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 109 appears in the next column

109. How often did you eat **doughnuts, sweet rolls, Danish,** or **pop-tarts**?

- ☐ NEVER (GO TO QUESTION 110)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

109a. Each time you ate **doughnuts, sweet rolls, Danish,** or **pop-tarts**, how much did you usually eat?

- ☐ Less than 1 piece
- ☐ 1 to 2 pieces
- ☐ More than 2 pieces

110. How often did you eat **sweet muffins** or **dessert breads** (including low-fat or fat-free)?

- ☐ NEVER (GO TO QUESTION 111)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

110a. Each time you ate **sweet muffins or dessert breads**, how much did you usually eat?

- ☐ Less than 1 medium piece
- ☐ 1 medium piece
- ☐ More than 1 medium piece

110b. How often were the sweet muffins or dessert breads you ate **light, low-fat,** or **fat-free sweet muffins** or **dessert breads**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

111. How often did you eat **fruit crisp, cobbler,** or **strudel**?

- ☐ NEVER (GO TO QUESTION 112)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 112 appears on the next page

Over the <u>past 12 months</u>...

111a. Each time you ate **fruit crisp, cobbler,** or **strudel,** how much did you usually eat?

- ☐ Less than ½ cup
- ☐ ½ to 1 cup
- ☐ More than 1 cup

112. How often did you eat **pie**?

- ☐ NEVER (GO TO QUESTION 113)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

112a. Each time you ate **pie**, how much did you usually eat?

- ☐ Less than ⅛ of a pie
- ☐ About ⅛ of a pie
- ☐ More than ⅛ of a pie

The next four questions ask about the kinds of pie you ate. Please read all four questions before answering.

112b. How often were the pies you ate **fruit pie** (such as apple, blueberry, others)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

112c. How often were the pies you ate **cream, pudding, custard,** or **meringue pie**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

112d. How often were the pies you ate **pumpkin** or **sweet potato pie**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 113 appears in the next column

112e. How often were the pies you ate **pecan pie**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

113. How often did you eat **chocolate candy**?

- ☐ NEVER (GO TO QUESTION 114)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

113a. Each time you ate **chocolate candy**, how much did you usually eat?

- ☐ Less than 1 average bar or less than 1 ounce
- ☐ 1 average bar or 1 to 2 ounces
- ☐ More than 1 average bar or more than 2 ounces

114. How often did you eat **other candy**?

- ☐ NEVER (GO TO QUESTION 115)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

114a. Each time you ate **other candy**, how much did you usually eat?

- ☐ Fewer than 2 pieces
- ☐ 2 to 9 pieces
- ☐ More than 9 pieces

115. How often did you eat **eggs, egg whites,** or **egg substitutes** (NOT counting eggs in baked goods and desserts)? *(Please include eggs in salads, quiche, and soufflés.)*

- ☐ NEVER (GO TO QUESTION 116)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

Question 116 appears on the next page

Over the <u>past 12 months</u>...

115a. Each time you ate **eggs**, how many did you usually eat?

- ☐ 1 egg
- ☐ 2 eggs
- ☐ 3 or more eggs

115b. How often were the eggs you ate **egg substitutes**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

115c. How often were the eggs you ate **egg whites only**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

115d. How often were the eggs you ate **regular whole eggs**?

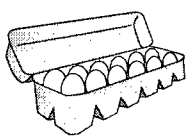
- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

115e. How often were the eggs you ate **cooked in oil, butter,** or **margarine**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

115f. How often were the eggs you ate part of **egg salad**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always



Question 116 appears in the next column

116. How many cups of **coffee**, caffeinated or decaffeinated, did you drink?

- ☐ NEVER (GO TO QUESTION 117)

- ☐ Less than 1 cup per month
- ☐ 1–3 cups per month
- ☐ 1 cup per week
- ☐ 2–4 cups per week
- ☐ 5–6 cups per week
- ☐ 1 cup per day
- ☐ 2–3 cups per day
- ☐ 4–5 cups per day
- ☐ 6 or more cups per day

116a. How often was the coffee you drank **decaffeinated**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

117. How many glasses of **ICED tea,** caffeinated or decaffeinated, did you drink?

- ☐ NEVER (GO TO QUESTION 118)

- ☐ Less than 1 cup per month
- ☐ 1–3 cups per month
- ☐ 1 cup per week
- ☐ 2–4 cups per week
- ☐ 5–6 cups per week
- ☐ 1 cup per day
- ☐ 2–3 cups per day
- ☐ 4–5 cups per day
- ☐ 6 or more cups per day

117a. How often was the iced tea you drank **decaffeinated** or **herbal tea**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

118. How many cups of **HOT tea**, caffeinated or decaffeinated, did you drink?

- ☐ NEVER (GO TO QUESTION 119)

- ☐ Less than 1 cup per month
- ☐ 1–3 cups per month
- ☐ 1 cup per week
- ☐ 2–4 cups per week
- ☐ 5–6 cups per week
- ☐ 1 cup per day
- ☐ 2–3 cups per day
- ☐ 4–5 cups per day
- ☐ 6 or more cups per day

118a. How often was the hot tea you drank **decaffeinated** or **herbal tea**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 119 appears on the next page

Over the <u>past 12 months</u>...

119. How often did you add **sugar** or **honey** to your coffee or tea?

- ☐ NEVER (GO TO QUESTION 120)
- ☐ Less than 1 cup per month
- ☐ 1–3 cups per month
- ☐ 1 cup per week
- ☐ 2–4 cups per week
- ☐ 5–6 cups per week
- ☐ 1 cup per day
- ☐ 2–3 cups per day
- ☐ 4–5 cups per day
- ☐ 6 or more cups per day

119a. Each time **sugar** or **honey** was added to your coffee or tea, how much was usually added?

- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

120. How often did you add **artificial sweetener** to your coffee or tea?

- ☐ NEVER (GO TO QUESTION 121)
- ☐ Less than 1 time per month
- ☐ 1–3 times per month
- ☐ 1 time per week
- ☐ 2–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2–3 times per day
- ☐ 4–5 times per day
- ☐ 6 or more times per day

120a. What kind of **artificial sweetener** did you usually use?

- ☐ Equal or aspartame
- ☐ Sweet N Low or saccharin

121. How often was **non-dairy creamer** added to your coffee or tea?

- ☐ NEVER (GO TO QUESTION 122)
- ☐ Less than 1 time per month
- ☐ 1–3 times per month
- ☐ 1 time per week
- ☐ 2–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2–3 times per day
- ☐ 4–5 times per day
- ☐ 6 or more times per day

121a. Each time **non-dairy creamer** was added to your coffee or tea, how much was usually used?

- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

Question 122 appears in the next column

121b. What kind of **non-dairy creamer** did you usually use?

- ☐ Regular powdered
- ☐ Low-fat or fat-free powdered
- ☐ Regular liquid
- ☐ Low-fat or fat-free liquid

122. How often was **cream** or **half and half** added to your coffee or tea?

- ☐ NEVER (GO TO QUESTION 123)
- ☐ Less than 1 time per month
- ☐ 1–3 times per month
- ☐ 1 time per week
- ☐ 2–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2–3 times per day
- ☐ 4–5 times per day
- ☐ 6 or more times per day

122a. Each time **cream** or **half and half** was added to your coffee or tea, how much was usually added?

- ☐ Less than 1 tablespoon
- ☐ 1 to 2 tablespoons
- ☐ More than 2 tablespoons

123. How often was **milk** added to your coffee or tea?

- ☐ NEVER (GO TO QUESTION 124)
- ☐ Less than 1 time per month
- ☐ 1–3 times per month
- ☐ 1 time per week
- ☐ 2–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2–3 times per day
- ☐ 4–5 times per day
- ☐ 6 or more times per day

123a. Each time **milk** was added to your coffee or tea, how much was usually added?

- ☐ Less than 1 tablespoon
- ☐ 1 to 3 tablespoons
- ☐ More than 3 tablespoons

123b. What kind of **milk** was usually added to your coffee or tea?

- ☐ Whole milk
- ☐ 2% milk
- ☐ 1% milk
- ☐ Skim, nonfat, or ½% milk
- ☐ Evaporated or condensed (canned) milk
- ☐ Soy milk
- ☐ Rice milk
- ☐ Other

Question 124 appears on the next page

Over the past 12 months...

124. How often was **sugar** or **honey** added to foods you ate? (Please do not include sugar in coffee, tea, other beverages, or baked goods.)

- ☐ NEVER (GO TO INTRODUCTION TO QUESTION 125)

- ☐ 1–6 times per year
- ☐ 7–11 times per year
- ☐ 1 time per month
- ☐ 2–3 times per month
- ☐ 1 time per week
- ☐ 2 times per week
- ☐ 3–4 times per week
- ☐ 5–6 times per week
- ☐ 1 time per day
- ☐ 2 or more times per day

124a. Each time **sugar** or **honey** was added to foods you ate, how much was usually added?

- ☐ Less than 1 teaspoon
- ☐ 1 to 3 teaspoons
- ☐ More than 3 teaspoons

The following questions are about the kinds of margarine, mayonnaise, sour cream, cream cheese, and salad dressing that you eat. If possible, please check the labels of these foods to help you answer.

125. Over the past 12 months, did you eat **margarine**?

- ☐ NO (GO TO QUESTION 126)
- ☐ YES

125a. How often was the margarine you ate **regular-fat margarine** (stick or tub)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

125b. How often was the margarine you ate **light** or **low-fat margarine** (stick or tub)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 126 appears in the next column

125c. How often was the margarine you ate **fat-free margarine**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

126. Over the past 12 months, did you eat **butter**?

- ☐ NO (GO TO QUESTION 127)
- ☐ YES

126a. How often was the butter you ate **light** or **low-fat butter**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

127. Over the past 12 months, did you eat **mayonnaise** or **mayonnaise-type dressing**?

- ☐ NO (GO TO QUESTION 128)
- ☐ YES

127a. How often was the mayonnaise you ate **regular-fat mayonnaise**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

127b. How often was the mayonnaise you ate **light** or **low-fat mayonnaise**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

Question 128 appears on the next page

Over the past 12 months...

127c. How often was the mayonnaise you ate **fat-free mayonnaise**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

128. Over the past 12 months, did you eat **sour cream**?

- ☐ NO (GO TO QUESTION 129)
- ☐ YES

128a. How often was the sour cream you ate **regular-fat sour cream**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

128b. How often was the sour cream you ate **light, low-fat, or fat-free sour cream**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

129. Over the past 12 months, did you eat **cream cheese**?

- ☐ NO (GO TO QUESTION 130)
- ☐ YES

129a. How often was the cream cheese you ate **regular-fat cream cheese**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

129b. How often was the cream cheese you ate **light, low-fat, or fat-free cream cheese**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

130. Over the past 12 months, did you eat **salad dressing**?

- ☐ NO (GO TO INTRODUCTION TO QUESTION 131)
- ☐ YES

130a. How often was the salad dressing you ate **regular-fat salad dressing** (including oil and vinegar dressing)?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

130b. How often was the salad dressing you ate **light or low-fat salad dressing**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

130c. How often was the salad dressing you ate **fat-free salad dressing**?

- ☐ Almost never or never
- ☐ About ¼ of the time
- ☐ About ½ of the time
- ☐ About ¾ of the time
- ☐ Almost always or always

The following two questions ask you to summarize your usual intake of vegetables and fruits. Please do not include salads, potatoes, or juices.

131. Over the past 12 months, how many servings of **vegetables** (not including salad or potatoes) did you eat per week or per day?

- ☐ Less than 1 per week
- ☐ 1–2 per week
- ☐ 3–4 per week
- ☐ 5–6 per week
- ☐ 1 per day
- ☐ 2 per day
- ☐ 3 per day
- ☐ 4 per day
- ☐ 5 or more per day

Question 130 appears in the next column

Over the past 12 months...

132. Over the past 12 months, how many servings of **fruit** (not including juices) did you eat per week or per day?

- ☐ Less than 1 per week
- ☐ 1–2 per week
- ☐ 3–4 per week
- ☐ 5–6 per week
- ☐ 1 per day
- ☐ 2 per day
- ☐ 3 per day
- ☐ 4 per day
- ☐ 5 or more per day

133. Over the past month, which of the following foods did you eat **AT LEAST THREE TIMES?** ***(Mark all that apply.)***

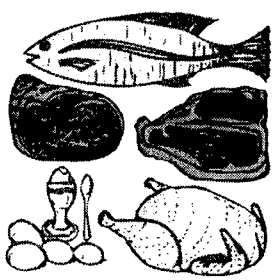
- ☐ Avocado, guacamole
- ☐ Cheesecake
- ☐ Chocolate, fudge, or butterscotch toppings or syrups
- ☐ Chow mein noodles
- ☐ Croissants
- ☐ Dried apricots
- ☐ Egg rolls
- ☐ Granola bars
- ☐ Hot peppers
- ☐ Jello, gelatin
- ☐ Milkshakes or ice-cream sodas
- ☐ Olives
- ☐ Oysters
- ☐ Pickles or pickled vegetables or fruit
- ☐ Plantains
- ☐ Pork neckbones, hock, head, feet
- ☐ Pudding or custard
- ☐ Veal, venison, lamb
- ☐ Whipped cream, regular
- ☐ Whipped cream, substitute
- ☐ NONE

134. For **ALL** of the past 12 months, have you followed any type of **vegetarian diet**?

- ☐ NO (GO TO INTRODUCTION TO QUESTION 135)
- ☐ YES

134a. Which of the following foods did you **TOTALLY EXCLUDE** from your diet? ***(Mark all that apply.)***

- ☐ Meat (beef, pork, lamb, etc.)
- ☐ Poultry (chicken, turkey, duck)
- ☐ Fish and seafood
- ☐ Eggs
- ☐ Dairy products (milk, cheese, etc.)



Introduction to Question 135 appears in the next column

The next questions are about your use of fiber supplements or vitamin pills.

135. Over the past 12 months, did you take any of the following types of **fiber or fiber supplements** on a regular basis (more than once per week for at least 6 of the last 12 months)? ***(Mark all that apply.)***

- ☐ NO, didn't take any fiber supplements on a regular basis (GO TO QUESTION 136)
- ☐ YES, psyllium products (such as Metamucil, Fiberall, Serutan, Perdiem, Correctol)
- ☐ YES, methylcellulose/cellulose products (such as Citrucel, Unifiber)
- ☐ YES, Fibercon
- ☐ YES, Bran (such as wheat bran, oat bran, or bran wafers)

136. Over the past 12 months, did you take any **multivitamins**, such as One-a-Day-, Theragran-, or Centrum-type multivitamins (as pills, liquids, or packets)?

- ☐ NO (GO TO INTRODUCTION TO QUESTION 138)
- ☐ YES

137. How often did you take **One-a-day-, Theragran-, or Centrum-type** multivitamins?

- ☐ Less than 1 day per month
- ☐ 1–3 days per month
- ☐ 1–3 days per week
- ☐ 4–6 days per week
- ☐ Every day

137a. Does your **multivitamin** usually contain **minerals** (such as iron, zinc, etc.)?

- ☐ NO
- ☐ YES
- ☐ Don't know

137b. For how many years have you taken **multivitamins**?

- ☐ Less than 1 year
- ☐ 1–4 years
- ☐ 5–9 years
- ☐ 10 or more years

Introduction to Question 138 appears on the next page

Over the past 12 months...

137c. Over the past 12 months, did you take any vitamins, minerals, or other herbal supplements other than your multivitamin?

☐ NO

Thank you *very much* for completing this questionnaire! Because we want to be able to use all the information you have provided, we would greatly appreciate it if you would please take a moment to review each page making sure that you:

- **Did not skip any pages and**
- **Crossed out the incorrect answer and circled the correct answer if you made any changes.**

☐ YES (GO TO INTRODUCTION TO QUESTION 138)

These last questions are about the vitamins, minerals, or herbal supplements you took that are NOT part of a One-a-day-, Theragran-, or Centrum-type of multivitamin.

Please include vitamins taken as part of an antioxidant supplement.

138. How often did you take **Beta-carotene** (**NOT** as part of a multivitamin in Question 137)?

☐ NEVER (GO TO QUESTION 139)
☐ Less than 1 day per month
☐ 1–3 days per month
☐ 1–3 days per week
☐ 4–6 days per week
☐ Every day

138a. When you took **Beta-carotene**, about how much did you take in one day?

☐ Less than 10,000 IU
☐ 10,000–14,999 IU
☐ 15,000–19,999 IU
☐ 20,000–24,999 IU
☐ 25,000 IU or more
☐ Don't know

138b. For how many years have you taken **Beta-carotene**?

☐ Less than 1 year
☐ 1–4 years
☐ 5–9 years
☐ 10 or more years

Question 139 appears in the next column

139. How often did you take **Vitamin A** (**NOT** as part of a multivitamin in Question 137)?

☐ NEVER (GO TO QUESTION 140)
☐ Less than 1 day per month
☐ 1–3 days per month
☐ 1–3 days per week
☐ 4–6 days per week
☐ Every day

139a. When you took **Vitamin A**, about how much did you take in one day?

☐ Less than 8,000 IU
☐ 8,000–9,999 IU
☐ 10,000–14,999 IU
☐ 15,000–24,999 IU
☐ 25,000 IU or more
☐ Don't know

139b. For how many years have you taken **Vitamin A**?

☐ Less than 1 year
☐ 1–4 years
☐ 5–9 years
☐ 10 or more years

140. How often did you take **Vitamin C** (**NOT** as part of a multivitamin in Question 137)?

☐ NEVER (GO TO QUESTION 141)
☐ Less than 1 day per month
☐ 1–3 days per month
☐ 1–3 days per week
☐ 4–6 days per week
☐ Every day

140a. When you took **Vitamin C**, about how much did you take in one day?

☐ Less than 500 mg
☐ 500–999 mg
☐ 1,000–1,499 mg
☐ 1,500–1,999 mg
☐ 2,000 mg or more
☐ Don't know

140b. For how many years have you taken **Vitamin C**?

☐ Less than 1 year
☐ 1–4 years
☐ 5–9 years
☐ 10 or more years

Question 141 appears on the next page

Over the past 12 months...

141. How often did you take **Vitamin E** (**NOT** as part of a multivitamin in Question 137)?

- ☐ NEVER (GO TO QUESTION 142)
- ☐ Less than 1 day per month
- ☐ 1–3 days per month
- ☐ 1–3 days per week
- ☐ 4–6 days per week
- ☐ Every day

141a. When you took **Vitamin E**, about how much did you take in one day?

- ☐ Less than 400 IU
- ☐ 400–799 IU
- ☐ 800–999 IU
- ☐ 1,000 IU or more
- ☐ Don't know

141b. For how many years have you taken **Vitamin E**?

- ☐ Less than 1 year
- ☐ 1–4 years
- ☐ 5–9 years
- ☐ 10 or more years

142. How often did you take **Calcium** or **Calcium-containing antacids** (**NOT** as part of a multivitamin in Question 137)?

- ☐ NEVER (GO TO QUESTION 143)
- ☐ Less than 1 day per month
- ☐ 1–3 days per month
- ☐ 1–3 days per week
- ☐ 4–6 days per week
- ☐ Every day

142a. When you took **Calcium** or **Calcium-containing antacids**, about how much elemental calcium did you take in one day? *(If possible, please check the label for elemental calcium.)*

- ☐ Less than 500 mg
- ☐ 500–599 mg
- ☐ 600–999 mg
- ☐ 1,000 mg or more
- ☐ Don't know

Question 143 appears in the next column

142b. For how many years have you taken **Calcium** or **Calcium-containing antacids**?

- ☐ Less than 1 year
- ☐ 1–4 years
- ☐ 5–9 years
- ☐ 10 or more years

The last two questions ask you about other supplements you took more than once per week.

143. Please mark any of the following **single supplements** you took more than once per week (**NOT** as part of a multivitamin in Question 137):

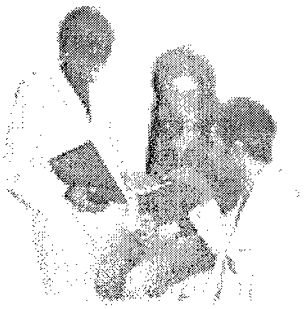
- ☐ B-6
- ☐ B-complex
- ☐ Brewer's yeast
- ☐ Cod liver oil
- ☐ Coenzyme Q
- ☐ Fish oil (Omega-3 fatty acids)
- ☐ Folic acid/folate
- ☐ Glucosamine
- ☐ Hydroxytryptophan (HTP)
- ☐ Iron
- ☐ Niacin
- ☐ Selenium
- ☐ Zinc

144. Please mark any of the following **herbal** or **botanical supplements** you took more than once per week.

- ☐ Aloe Vera
- ☐ Astragalus
- ☐ Bilberry
- ☐ Cascara sagrada
- ☐ Cat's claw
- ☐ Cayenne
- ☐ Cranberry
- ☐ Dong Kuai (Tangkwei)
- ☐ Echinacea
- ☐ Evening primrose oil
- ☐ Feverfew
- ☐ Garlic
- ☐ Ginger
- ☐ Ginkgo biloba
- ☐ Ginseng (American or Asian)
- ☐ Goldenseal
- ☐ Grapeseed extract
- ☐ Kava, kava
- ☐ Milk thistle
- ☐ Saw palmetto
- ☐ Siberian ginseng
- ☐ St. John's wort
- ☐ Valerian
- ☐ Other

Thank you *very much* for completing this questionnaire! Because we want to be able to use all the information you have provided, we would greatly appreciate it if you would please take a moment to review each page making sure that you:

- **Did not skip any pages and**
- **Crossed out the incorrect answer and circled the correct answer if you made any changes.**



Study Objectives

The Lombardi Cancer Center at Georgetown University Medical Center, in collaboration with the Washington Hospital Center, is conducting a study on prostate cancer. The main goal of the project is to determine susceptibility to prostate cancer by evaluating a person's ability to repair DNA damage. For this purpose, the researchers are collecting small samples of blood, saliva, nail clipping and urine as well as information about family history, diet, exercise, drinking and smoking habits. These specimen and the collected information will be available to qualified medical researchers for studies examining biological factors linked to prostate cancer susceptibility.

Despite its morbidity and mortality, very little is known about the causes of prostate cancer. Clinical observations suggest that certain biological factors put individuals at increased risk for this disease. The ability to identify such risk factors will have a major impact on cancer prevention and treatment.

We are presently recruiting healthy men and prostate cancer patients to be participants in the study. The purpose is to compare a group of cancer-free subjects to prostate cancer patients in an effort to determine genetic susceptibility to the disease. You can advance prostate cancer research by joining the study. Our professional staff will make sure to accommodate your schedule and needs to ensure that this is a pleasant experience for you. In addition, you will be notified when the results of the study become available.

Research

Cancer research gives hope. Doctors and researchers at hospitals and medical centers all across the country are learning more about what causes prostate and are exploring ways to prevent it. They are also looking for better ways to detect, diagnose, and treat this disease.

When cancer is found and treated early, the chances for survival are better. The data collected in this study is analyzed for susceptibility in DNA repair and will be available to qualified researchers as a resource for discovery of prostate cancer biomarkers. These biomarkers may be able to identify susceptible subpopulations where cancer prevention, screening, and treatment methods may be focused. They will also help scientists and doctors develop advanced prevention methods leading to decreased occurrence of this disease.

What is Prostate Cancer?

In the United States prostate cancer is the most commonly diagnosed non-skin cancer among men and it is the second most common cause of cancer deaths. In recent years, prostate cancer has become a worldwide public health concern and disease incidence is increasing in all populations. For this reason it is essential that all risk factors possibly contributing to this disease are studied.

Cancer is a group of many different diseases that all arise in cells, the body's basic unit of life. The body is made up of many types of cells. Normally cells grow and divide to produce more cells only when the body needs them. This orderly process helps keep the body healthy. Sometimes cells keep dividing when new cells are not needed. These cells may form a mass of extra tissue called a growth or tumor. Tumors can be benign or malignant.

How to Become Involved

You may become involved in this study if you:

- are living in the greater Washington DC area including Maryland and Virginia
- have no prior cancer history

OR

- are a prostate cancer patient
- are over the age of 18

Upon contact, we will inform you about the study and verify your eligibility to participate. We will collect information about your alcohol and tobacco history, occupational history, family history, diet and exercise. You will be asked to donate a small sample of blood, urine, saliva, nail clipping and the left over tumor tissue that may have been removed if you are a cancer patient. Contact us at any time if you need more information or decide to participate. You can enter the study right now as you are waiting in the clinic by calling the number below or by notifying clinic staff.

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